Effekter av träning i traumaomhändertagande på utfall hos vuxna traumapatienter: en klusterrandomiserad studie

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Grundansökan
Ansökan rör forskning inom Medicin och hälsovetenskap
Avslutad

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1. Huvudsakliga uppgifter

1.2 Sökande huvudman för forskningen

Karolinska Institutet

1.3 Behörig företrädare för forskningshuvudmannen

Marie Elisabet Klang Hasselberg

1.3.1 Ange en titel för behörig företrädare - titel ska innebära ett verksamhetsansvar

Prefekt

1.4 Kommer flera forskningshuvudmän att medverka i forskningsprojektet?

Nej

1.5 Hemvist för forskningen

Institutionen för global folkhälsovetenskap

1.6 Ansvarig forskare för projektet

Martin Knut Erik Filippus Gerdin Wärnberg

1.6.1 Institution/hemvist som ansvarig forskare är verksam vid

Institutionen för global folkhälsovetenskap

1.7 Är den ansvariga forskaren disputerad?

Ja

Frågor för avgiftskategori

1.9 Hur många forskningshuvudmän kommer att ingå i forskningsprojektet?

En

1.10 Innefattar forskningen endast behandling av personuppgifter?

Ja

2. Typ av forskning – initiala frågor

2.1 Gör en egen bedömning och ange på vilka punkter nedan som forskningen omfattas av 3-4 §§ etikprövningslagen. Observera att myndigheten kan komma att göra en annan bedömning.

✓ 3 § 1 Forskningen innefattar behandling av känsliga personuppgifter.

2.1.1 [Om 3 § 1] Gör en egen bedömning och ange vilken typ av känsliga personuppgifter som kommer att behandlas i projektet. Observera att myndigheten kan komma att göra en annan bedömning.

✓ hälsa

2.2 Önskas ett rådgivande yttrande?

Ja

2.3 Välj ämnesklassificering

2.3.3 Medicin och hälsovetenskap

✓ 30302 Folkhälsovetenskap, global hälsa, socialmedicin och epidemiologi

2.4 Gäller studien klinisk forskning?

Ja

2.4.1 Vilken/vilka diagnoskoder avser forskningen (ICD-10-SE)

✓ S00-T98 Skador, förgiftningar och vissa andra följder av yttre orsaker

2.4.1.19 Avsnitt - Skador, förgiftningar och vissa andra följder av yttre orsaker

✓ S00-S09 Skador på huvudet
✓ S10-S19 Skador på halsen
✓ S20-S29 Skador i bröstregionen
✓ S30-S39 Skador i buken, nedre delen av ryggen, ländkotpelaren och bäckenet
✓ S40-S49 Skador på skuldra och överarm
✓ S50-S59 Skador på armbåge och underarm
✓ S60-S69 Skador på handled och hand
✓ S70-S79 Skador på höft och lår
✓ S80-S89 Skador på knä och underben

✓ S90-S99 Skador på fotled och fot
✓ T00-T07 Skador som engagerar flera kroppsregioner
✓ T08-T14 Skador på icke specificerad del av bålen, extremitet eller annan kroppsregion
✓ T15-T19 Effekter av främmande kropp som trängt in genom naturlig öppning
✓ T20-T32 Brännskador och frätskador
✓ T33-T35 Köldskada
✓ T51-T65 Toxisk effekt av substanser med i huvudsak icke-medicinsk användning
✓ T66-T78 Andra och ospecificerade effekter av yttre orsaker
✓ T79-T79 Vissa tidiga komplikationer till skada genom yttre våld

2.4.2 Vilken studietyp beskriver bäst den aktuella studien?

✓ Intervention

2.5 Särskilda frågor för medicinsk forskning

2.5.1 Avser ansökan forskning som inbegriper äggdonation?

Nej

2.5.2 Avser ansökan forskning med xenogen cellterapi?

Nej

2.5.3 Kommer joniserande strålning ingå i forskningsprojektet?

Nej

2.5.4 Kommer biologiskt material att användas i projektet?

Nej

2.5.5 Avser forskningen klinisk prövning eller en prestandastudie av medicinteknisk produkt/medicinteknisk produkt för in vitro-diagnostik?

Nej

3. Syfte och frågeställningar

3.1 Skriv en populärvetenskaplig sammanfattning av forskningsprojektet.

Varje år dör 4.3 miljoner människor av trauma, alltså svår kroppskada som orsakas av olyckor eller våld. Trauma är den främsta orsaken till sjukdomsbörda bland unga vuxna. Ett bra primärt omhändertagande, alltså vård tidigt efter skadan, är avgörande för att rädda liv och minska sjuklighet. Flera kurser har tagits fram för att förbättra det primära omhändertagandet. Den mest kända kursen är Avanced Trauma Life Support® (ATLS®), och mer än en miljon läkare över hela världen har utbildats i ATLS® sedan 1978.

Trots att ATLS används i så stor omfattning finns det ingen forskning av hög kvalitet som visar att ATLS® förbättrar utfallen hos patienter. Detta är problematiskt eftersom det betyder att många länder, inklusive Sverige, spenderar miljontals kronor varje år på att utbilda läkare i ATLS® utan att veta om det leder till förbättrad överlevnad eller minskad sjuklighet hos patienter.

Vi vill därför studera om ATLS® förbättrar överlevnad och minskar sjuklighet hos vuxna traumapatienter. Vi genomför projektet i Indien eftersom ATLS® inte är standard där än. I vårt projekt kommer vi att slumpa sjukhus till olika tidpunkter när de ska införa ATLS®. Vi kommer att samla in data från patienter under en period innan sjukhusen inför ATLS® och sedan under en period efter att de inför ATLS®. Vi kommer därefter att jämföra utfall hos patienter innan och efter införandet av ATLS®.

Vårt projekt blir det första att utvärdera effekten av ATLS® på utfall hos patienter genom storskalig forskning av hög kvalitet. Kunskapen som genereras från vårt projekt är viktig oavsett om resultaten är positiva eller negativa. Om vi visar att ATLS® förbättrar överlevnad och minskar sjuklighet bör ATLS® eller liknande kurser införas i större skala. Om vi visar att ATLS® inte förbättrar överlevnad och minskar sjuklighet behövs nya sätt att träna det primära omhändertagandet av traumapatienter.

3.2 Vad är det vetenskapliga syftet med projektet?

Det övergripande vetenskapliga syftet med projektet är att jämföra effekten av vård efter träning av läkare i ATLS® med vård innan träning av läkare i ATLS® på patientutfall.

Forskningsproblemet är trauma, här definierat som fysiskt kroppskada i kombination med kroppens svar på sådan skada. Varje år dör över fyra miljoner människor till följd av trauma, och det är den vanligaste dödsorsaken hos unga människor. Felaktig handläggning under det initiala omhändertagandet anges ofta som den vanligaste orsaken till förebyggbar död bland traumapatienter som når sjukhus.

Flera kurser och träningsprogram har utvecklats för att förbättra det initiala omhändertagandet av traumapatienter. ATLS® är det mest välkända och spridda träningsprogrammet där läkare utbildas i ett strukturerat initialt omhändertagande av traumapatienter. Hittills har mer än en miljon läkare i fler än 80 länder genomgått ATLS®-träning sedan den första kursen genomfördes 1978.

Åtminstonde tre randomiserade och åtskilliga observationella studier har visat att träning i ATLS® leder till att läkare förbättrar sina teoretiska kunskaper och praktiska färdigheter vad gäller det initiala traumaomhändertagandet. Flera observationella studier indikerar också att ATLS® leder till minskad dödlighet, även om enstaka studier har visat en högre dödlighet bland patienter som handläggs av läkare som tränats i ATLS® än de som inte gjort det.

Ett flertal systematiska literaturöversikter har genomförts för att kvantifiera effekten av ATLS® på patientutfall, men ingen av dessa har kunnat identifiera någon studie av hög kvalitet. De efterlyser därför kontrollerade prövningar i kontexter där ATLS® inte är standard än, för trots bristen på evidens av hög kvalitet är genomgången träning i ATLS® i det närmaste obligatoriskt för läkare som händlägger traumapatienter i många delar av världen.

3.3 Vilka är de vetenskapliga frågeställningarna?

Den vetenskapliga frågeställning är hurvida patientutfall, som dödlighet och sjuklighet, förändras efter att läkare tränas i ATLS® jämfört med innan de tränas i ATLS®.

3.4 Kommer delar av den forskning som beskrivs i ansökan ske utanför Sverige?

Ja

3.4.1 [Om Ja 3.4] Vilka delar av forskningen kommer ske helt eller delvis i Sverige?

✓ Genomförande av analys
✓ Genomförande av bearbetning.

3.4.2 [Om Ja 3.4] Vilka delar av forskningen kommer ske helt eller delvis utanför Sverige?

✓ Rekrytering av forskningspersoner
✓ Inhämtande av underlag
✓ Genomförande av försök

3.4.3 [Om Ja 3.4] Beskriv hur de delar av forskningen som sker utanför Sverige kommer att genomföras.

Studien är en klusterrandomiserad klinisk prövning som genomförs vid sjukhus i Indien. I en klusterrandomiserad studie sker inte randomiseringen på individnivå, som vid en klassisk randomiserad läkemedelsprövning, utan på en högre nivå, i detta fall på sjukhusnivå. I denna typ av prövning tar alla sjukhus del av interventionen, alltså ATLS®-träning, men tidpunkten när när träningen sker randomiseras. Varje sjukhus deltar 13 månader i studien.

Studien har inklusionskriterer både nivån av enheten som ska randomiseras och på patientnivå. Vi inkluderar sjukhus i Indien som lägger in åtminsone 400 traumapatienter per år. Vid varje sjukhus tränas läkare som initialt händlägger traumapatienter på akutmottagningen. Vi inkluderar patienter som är 15 år eller äldre och som läggs in på grund av trauma. Vi exkluderar patienter med isolerad skada på armar eller ben.

Inklusion av patienter sker på akutmottagningen vid deltagande sjukhus. Vid varje sjukhus finns en forskningskoordinator som samlar in data, informerar om studien och inhämtar samtycke när detta är tillämpligt. Majoriteten av datan som samlas in kommer från patientjournaler och är rutinmässigt registrerat, inklusive det primära utfallsmåttet. Delar av datan inhämtas via intervjuer eller direkt observation av vården.

Det primära utfallsmåttet är död på sjukhus inom 30 dagar från ankomst till akutmottagningen. Sekundära utfallsmått är död inom 24 timmar samt inom 30 och 90 dagar från ankomst till akutmottagningen, villket inkluderar även död utanför sjukhus, samt livskvalitet,

funktionsnedsättning, vårdtid, intensivvård, återgång till arbete och följsamhet till initialt omhändertagande enligt ATLS® -principer.

Vi samlar även in data på ålder, kön, komorbiditeter, övrig demografi, vitalparameterar, undersökningar och operationer och skador. All data samlas in och lagras pseudonymiserad via mjukvaran REDCap på säkra servrar vid den koordinerande organisationen i Indien, vilket är the George Institute for Global Health.

4. Metod

Frågor i nedanstående avsnitt ska bara besvaras avseende den forskning som ska ske i Sverige

4.1 Redogör för metod inkl. proceduren, tekniken eller behandlingen.

Här beskrivs endast metoder för att beskriva data och den statistiska metoden, eftersom det är dessa delar som kommer att ske i Sverige. Insamlad kontinuerlig data kommer att beskrivas med hjälp av deskriptiv statistik. Huvudanalysen avseende effekten av ATLS® -träning på patientutfall kommer att ske med en multivariatmodell som tar hänsyn till att data är klustrad inom sjukhus och grupper av sjukhus samt att den är insamlad över tid. I första hand kommer modellen vara en binär multivariatmodell som generar en oddskvot som mått på effekten av ATLS® -träning på död inom 30 dagar på sjukhus, men vi kommer även att utforska andra modeller, i första hand en multivariatmodell för att generera en skillnad i risk för död mellan patienter som behandlas efter att läkarna tränats i ATLS® -träning jämfört med innan. Övriga binära utfall kommer att analyseras med liknande modeller. Utfall med fler än två kategorier kommer att analyseras med ordinala eller nominala multivariata modeller. Kontinuerliga utfall analyseras med linjära modeller. Vi kommer även att analysera effekten av interventionen i olika subgrupper, som till exempel män och kvinnor, äldre, patienter med svårt trauma, genomföra sensitivitetsanalyser där vi utvärderar hur olika typer av modellstrukturer påverkar resultaten, samt sambanden mellan olika variabler och utfall.

4.2 Om forskningen går ut på att pröva en ny metod eller behandling: Redogör för på vilket sätt metoden skiljer sig från den ordinarie verksamheten.

Denna del av forskningen sker inte i Sverige.

4.3 Redogör för tidigare erfarenheter (egna och/eller andras) av den valda metoden.

Vi har omfattande erfarenhet av klinisk epidemiologisk forskning och multivariabelmodeller men analyser av denna typ av klusterprövningar är nya för den huvudansvariga forskaren och deltagande biostatistiker vid Karolinska Institutet. I projektgruppen deltar därför en professor i biostatistik vid University of Birmingham i Storbritannien som leder ett forskningsprogram på denna typ av prövningar och hur de ska analyseras. Denna deltagande forskare kommer att handleda forskare vid Karolinska Institutet i genomförandet av analysen.

5. Tidsplan

Frågor i nedanstående avsnitt ska bara besvaras avseende den forskning som ska ske i Sverige

5.1 Förväntat startdatum för projektet:

2025-01-31

5.2 Förväntat slutdatum för projektet:

2029-12-31

5.3 Tidsplan för de olika delar som ingår i projektet:

Här beskrivs tidsplanen för de delar av forskningen som sker i Sverige, alltså datahantering och analys. Data förväntas överföras till Sverige tidigast i februari 2025. Data kommer att sammanfattas inför regelbundna möten i prövningens projekt-, styr- och dataöversiktsgrupper. Projektgruppen träffas varje till var sjätte månad och förses inför möten med en översiktig beskrivning av hittills insamlad data. Styr- och dataöversiktsgruppen träffas ungefär årligen och får även den en sammanfattning av datan inför sina möten. Den slutgiltiga dataanalysen planeras ske under 2029.

6. Datainsamling

Frågor i nedanstående avsnitt ska bara besvaras avseende den forskning som ska ske i Sverige

6.1 Redogör för datainsamling och datas karaktär.

Här beskrivs endast insamlad datas karaktär, eftersom enbart datahantering och analys ska ske i Sverige. Datainsamling sker i Indien och beskrivs därför inte. Datan som samlas in delas in i olika faser. Som grunddata inhämtas information om ålder, kön, civilstatus, utbildningsnivå, arbete och/eller studier, inkomstnivå, skademekanism, skörhet och komorbiditeter in.

Angående perioden från skadan till inkomst till sjukhus samlar vi in data på tidpunkten för skadan, hur transporten till sjukhus skedde, samt om deltagaren remitterades från en annan vårdinstans. På akutmottagningen samlar vi in information om följsamhet till handläggning enligt ATLS® -principer, samt vilka åtgärder som genomförs i enlighet med dessa principer. Vi samlar också in data på tidpunkten för ankomst till akutmottagningen, samt blodtryck, hjärtfrekvens, andningsfrekvens, medvetandegrad, kroppstemperatur, syrgasnivåer i blodet, samt status när deltagaren lämnar akutmottagningen, alltså huruvida patienten levde eller överförs till annat sjukhus.

Efter inläggning samlar vi in data om tidpunkt för inläggning och vilken avdelning patienten läggs in på. Vi registrerar om patienten intensivvårdas samt status när patienten lämnar sjukhuset, inklusive om patienten överförs till ett annat sjukhus för fortsatt vård. Vi samlar in data på genomförda operationer, bildundersökningar som slätröntgen, datortomografi eller ultraljud, transfusioner av blodprodukter och tidpunkten för dessa åtgärder. Vi registrerar även alla skador som diagnosticeras och klassificerar dessa enligt ICD 10.

Som uppföljning samlar vi in data på livskvalitet genom instrumentet EQ5D5L, som innehåller frågor om rörlighet, egenvård, dagliga aktiviteter, smärta, depression och nedstämdhet samt en

sammanfattning bedömning av hälsostatus vid tidpunkten för uppföljningen. Vi följer också upp deltagare avseende funktionsnedsättning med hjälp av instrumentet WHODAS 2.0, vilket inkluderar frågor om svårigheter med att stå längre stunder, ta hand om hushållet, lära sig nya uppgifter, medverka vid sociala sammankomster, hur man påverkats känslomässigt, koncentration, gå en längre distans, tvätta sig, klä på sig, träffa nya människor, bibehålla vänskaper, arbeta eller studera, samt hur ofta svårigheter med ovanstående var närvarande. Vi samlar också vi in data på återgång till arbete.

Till sist innehåller data uppgifter om säkerhetsincidenter, vilket vi definierar som mekanisk ventilation – alltså respiratorbehandling – under längre tid än 7 dagar, dialysstart, användning av blodtryckshöjande läkemedel (så kallade vasopressorer) under mer än två dagar, eller förnyad användning av sådana efter ett uppehåll under minst två dagar. Denna data samlas in för att kunna upptäcka komplikationer från lungor, njurar eller infektiösa komplikationer.

6.2 Redogör för de beräkningar och/eller överväganden som motiverar undersökningsmaterialets storlek.

Eftersom de beräkningar och överväganden som motiverar undersökningsmaterialets storlek är avgörande för mängden data som kommer att hanteras i Sverige beskrivs de här. För att kunna upptäcka en skillnad i det primära utfallsmåttet död på sjukhus inom 30 dagar från ankomst till akutmottagningen mellan 20% innan ATLS® -träning till 15% efter ATLS® -träning med 90% power och en signifikansnivå på 5% krävs att 30 sjukhus deltar och att varje sjukhus inkluderar åtminstone 12 patienter per månad som de deltar I studien. Detta innebär att det totala undersökningsmaterialets storlek blir åtminstone 4320 patienter, men det kan bli större beroende på hur många patienter som inkluderas vid varje sjukhus, eftersom oberoende av antalet patienter som rekryteras krävs att varje sjukhus deltar alla 13 månader. Frekvensen av det primära utfallsmåttet kommer från våra tidigare studier vid indiska sjukhus och den uppskattade effektstorleken bygger på en systematisk litteraturöversikt och metaanalys av observationella studier av sambandet mellan ATLS® -träning och död som vi genomfört som en del av planeringen av den här studien.

6.3 Hur kommer undersökningsprocedurerna att dokumenteras?

Beskrivs ej eftersom detta ej sker i Sverige.

6.4 Hur kommer insamlade data att hanteras och förvaras?

Insamlad data kommer att överföras pseudonymiserad till från servrar vid the George Institute for Global Health i Indien till en server vid Karolinska Institutet. Servern vid Karolinska Institutet är endast åtkomlig med hjälp av multifaktorautentisering över ett så kallat virtuellt privat nätverk (VPN). Data varken lagras eller hanteras på lokala datorer utan all hantering och analys sker i servermiljön. Kodnyckeln förvaras vid the George Institute for Global Health och överförs ej till Sverige. Datan sparas, arkiveras och gallras enligt gällande regelverk.

7. Etiska överväganden

Frågor i nedanstående avsnitt ska bara besvaras avseende den forskning som ska ske i Sverige

7.1 Vilka risker kan ett deltagande medföra för de forskningspersoner som ingår i forskningsprojektet?

Den risk som den forskning som sker i Sverige medför för forskningspersoner som ingår i forskningsprojeketet är felaktig spridning och användning av data.

7.2 Vilken nytta kan ett deltagande medföra för de forskningspersoner som ingår i forskningsprojektet?

Här beskrivs även nyttan som de delar av forskningen som bedrivs utanför Sveriga kan medföra för forskningspersonerna, eftersom de är relevanta för värderingen av förhållandet mellan riskerna och nyttan av projektet som helhet.

Forskningspersonerna som inkluderas efter att läkarna genomgått ATLS® -träning kan potentiellt få direkt nytta av ett förbättrat initialt omhändertagande, med minskad risk för död och sjuklighet. Som grupp har forskningspersonerna potentiell nytta av den kunskap som genereras av projektet vad gäller hur det initiala traumaomhändertagandet kan förbättras.

7.3 Gör en värdering av förhållandet mellan riskerna och nyttan av projektet.

Med anledning av hur projektet har utformats för att minimera riskerna för forskningspersonerna, vilket beskrivs nedan, bedöms nyttan överstiga riskerna eftersom risken för felaktig spridning och användning av data bedöms som mycket lite, medan nyttan är potentiellt påtaglig.

7.4 Beskriv hur projektet har utformats för att minimera riskerna för forskningspersonerna.

Här beskrivs hur risken för felaktig spridning och användning av data minimeras eftersom det är denna risk som identifierats vad gäller den del av forskningen som sker i Sverige. För det första är data pseudonymiserad och kodnyckeln finns inte i Sverige, vilket minskar risken för att enskilda forskningspersoner identifieras. Data lagras aldrig på egna datorer utan båda hanteras och analyseras på en server vid Karolinska Institutet. Denna server kan nås på distans, men för åtkomst krävs multifaktorautentisering över ett virtuellt privat nätverk, vilket alltså innebär att det krävs många nivåer av lösenord och digitala nycklar för att komma åt datan. Åtkomst till datan loggas och den lagras krypterat när den inte används. Med anledning av dessa åtgärder bedöms risken för felaktig spridning och användning av datan som mycket låg.

7.5 Identifiera och precisera om eventuella etiska problem (nackdelar/fördelar) kan uppstå i ett vidare perspektiv genom forskningsprojektet.

Risken för nackdelar i ett vidare perspektiv bedöms som mycket låg. Interventionen, alltså ATLS® -träning av läkare, är väl etablerad och används som rutin i stora delar av världen. Risken att interventionen skulle vara skadlig är därför mycket liten. Risken för nackdelar vid ett negativt resultat, alltså att vi inte finner att ATLS® -träning leder till förbättrade utfall, bedöms också som mycket liten. Istället bör ett sådant resultat innebära att ny forskning och utvecklingsarbete

fokuserar på hur utbildning och träning i initialt traumaomhändertagande bör ske istället. Detta kan potentiellt leda till förbättrad vård för traumapatienter på lång sikt. Vid ett positivt resultat bör vidare forskning och utvecklingsarbete fokusera på hur ATLS® -träning kan göras tillgänglig för fler läkare och patienter på ett sätt som är kostnadseffektivt och hållbart. Därför bör även ett sådant resultat leda till fördelar i ett vidare perspektiv.

8. Forskningspersoner

Frågor i nedanstående avsnitt ska bara besvaras avseende den forskning som ska ske i Sverige

8.1 Hur görs urvalet av forskningspersoner?

Urvalet sker ej i Sverige och beskrivs därför inte här.

8.2 Hur många forskningspersoner kommer att inkluderas i Sverige?

0

8.3 Ange ålder på forskningspersoner som kommer att inkluderas i projektet.

✓ 0-17
✓ 18-64
✓ 65+

8.4 Ange kön på de forskningspersoner som kommer att inkluderas i projektet.

✓ Kvinna
✓ Man
✓ Annan

8.5 Vilka urvalskriterier kommer att användas för inklusion?

Dessa beskrivs här eftersom de påverkar vilken data som hanteras i Sverige. Vi inkluderar patienter som är 15 år eller äldre och som antingen 1) läggs in eller 2) överförs från akutmottagningen till annan vårdinrättning för inläggning eller 3) avlider mellan ankomst och inläggning vid deltagande sjukhus vid tidpunkten när en ATLS® -tränad läkare finns på plats för att genomföra det initiala omhändertagandet. Trauma definieras med hjälp av kapitel 20 i ICD 10. Skadetillfället måste vara inom 48 timmar från ankomst till akutmottagningen.

8.6 Vilka urvalskriterier kommer att användas för exklusion?

Dessa beskrivs här eftersom de påverkar vilken data som hanteras i Sverige. Vi exkluderar patienter med isolerad skada på armar och ben samt patienter som läggs in direkt utan att passera akutmottagningen.

8.7 Ange relationen mellan forskare och forskningspersonerna.

Forskare i Sverige har ingen direkt relation till forskningspersonerna, förutom att de inkluderas vid sjukhus som deltar i prövningen.

8.8 Vilket försäkringsskydd finns för de forskningspersoner som deltar i forskningsprojektet?

Inget försäkringsskydd behövs för den del av forskningen som sker i Sverige.

8.9 Redogör för den beredskap som finns för att hantera oväntade bifynd eller händelser under forskningsprocessen som kan äventyra forskningspersonernas hälsa, säkerhet och personlig integritet.

Ej applicerbart för den del av forskningen som sker i Sverige.

8.10 Kommer ekonomisk ersättning eller andra förmåner betalas ut till forskningspersonerna?

Nej

9. Information och samtycke

Frågor i nedanstående avsnitt ska bara besvaras avseende den forskning som ska ske i Sverige

9.1 Kommer forskningspersonerna att informeras om forskningsprojektet och tillfrågas om de vill vara med eller inte?

Nej

9.1.2 [Om Nej 9.1] Motivera varför forskningspersonerna inte ska informeras och tillfrågas.

Eftersom studien är klusterrandomiserad kan forskningspersonerna ej tacka nej till att ta del av interventionen. De tillfrågas dock om de tillåter att deras data används i forskningen. Delar av datan samlas in under förmodat samtycke, men forskningspersonerna informeras om detta och erbjuds möjligheten att få sin data exkluderad. Andra delar av datan samlas in med informerat samtycke. Beskrivs ej mer i detalj här då detta ej sker i Sverige.

9.2 Ni har fyllt i att barn under 18 år kommer att ingå i forskningsprojektet, ange ålder:

✓ 15-17

9.3 Kommer forskningspersoner, vars mening på grund av sjukdom, psykisk störning, försvagat hälsotillstånd eller något annat liknande förhållande inte kan inhämtas, att ingå i forskningsprojektet?

Ja

9.3.1 [Om Ja 9.3] Motivera varför denna grupp av forskningspersoner ska ingå i projektet.

Forskningen handlar om att förbättra vården för svårt skadade personer. De mest svårt skadade är ofta inte i ett tillstånd där de kan ta ställning till forskningen, till exempel på grund av hjärnskada eller fysisk chock, samtidigt som de har den största potentiella nyttan av forskningen. Det är därför avgörande att inkludera denna grupp av personer. De kommer därför att inkluderas men informeras och erbjudas samma möjligheter att få sin data exkluderad som andra forskningspersoner när de återfår medvetande. Beskrivs ej mer i detalj här då detta ej sker i Sverige.

9.3.2 [Om Ja 9.3] Beskriv hur samråd med närmaste anhöriga, god man eller förvaltare kommer att ske.

Beskrivs ej här då detta ej sker i Sverige.

10. Registeruppgifter

Frågor i nedanstående avsnitt ska bara besvaras avseende den forskning som ska ske i Sverige

10.1 Kommer projektet att begära ut uppgifter från ett befintligt register?

Nej

11. Resultat från djurförsök

Frågor i nedanstående avsnitt ska bara besvaras avseende den forskning som ska ske i Sverige

11.1 Finns det relevanta resultat från djurförsök?

Ej aktuellt

12. Redovisning av resultat

Frågor i nedanstående avsnitt ska bara besvaras avseende den forskning som ska ske i Sverige

12.1 Hur garanteras tillgång till data för forskningshuvudmannen och medverkande forskare?

Tillgång till data för forskningshuvudmannen och medverkande forskare garanteras genom avtal mellan Karolinska Institutet och the George Institute for Global Health i Indien.

12.2 Vem eller vilka ansvarar för databearbetning och skriftlig redovisning av resultaten?

Den huvudansvariga forskaren ansvara för databearbetning och skriftlig redovisning av resultaten.

12.3 Hur och när planeras resultaten att offentliggöras?

Resultaten planeras att offentliggöras genom vetenskaplig publicering med peer review och open access. Resultaten kommer också att offentliggöras genom att de registreras i öppna forskningsdatabaser. Offentliggörandet av huvudresultaten förväntas ske inom ett år från avslutandet av projektet.

12.4 På vilket sätt garanteras forskningspersonernas rätt till integritet när materialet offentliggörs?

Forskningspersonernas rätt till integritet garanteras genom att data vid vetenskaplig publicering och registrering i publika databaser redovisas på gruppnivå. Vid eventuell publicering av individuell patientdata kommer den att vara anonymiserad utan koppling till kodnyckel.

13. Ekonomiska förhållanden

Frågor i nedanstående avsnitt ska bara besvaras avseende den forskning som ska ske i Sverige

13.1 Är forskningen företagsinitierad?

Nej

13.2 Hur kommer forskningsprojektet att finansieras?

✓ Bidrag från svensk statlig myndighet eller forskningsråd
✓ Bidrag från svensk stiftelse, fond eller liknande
✓ Bidrag från utländsk myndighet, stiftelse, fond eller liknande

13.3 Redovisa eventuella ekonomiska överenskommelser med bidragsgivare eller andra finansiärer (namn och belopp).

I dagsläget har överenskommelser om finansiering slutits med Vetenskapsrådet (7,550,000 kr) och Laerdal Foundation (400,000 kr). Denna finansiering räcker inklusion av de första tio sjukhusen samt datahantering och analys. Vi ansöker kontinuerligt om ytterligare anslag.

13.4 Redovisa forskningshuvudmannens, ansvarig forskares och medverkande forskares egna ekonomiska intressen.

I dagsläget finns inga egna ekonomiska intressen hos forskningshuvudmannen eller den ansvariga forskaren i detta projekt. Flera forskare som deltar i projektet är själva instruktörer i ATLS eller andra liknande träningsprogram.

Forskningsplan

Den sammanfattande beskrivningen av forskningsprojektet ska förstås av fackmän. Den kan lämpligen utformas enligt följande:
Vetenskaplig frågeställning: En redogörelse för det övergripande syftet med det föreslagna forskningsprojektet samt specifika mål (primära och sekundära frågeställningar).
Områdesöversikt: Ge ett sammandrag av egna och andras forskning och tidigare resultat inom forskningsområdet. Översikten ska tydliggöra det aktuella projektets relevans. Nyckelreferenser

ska anges.
Projektbeskrivning: Gör en sammanfattning av projektets/motsvarande uppläggning. Urval av forskningspersoner, procedurer, metoder med mera ska tydligt redovisas. Det ska framgå hur metoder, urval och procedurer kan ge svar på de specifika frågeställningarna. Om flera delprojekt avses anges sekvens för genomförande och på vilket sätt ett efterföljande delprojekts uppläggning kan bero av resultaten av ett föregående.
Betydelse: Ge en kortfattad redogörelse för projektets betydelse för forskningsområdet.
Preliminära resultat: Kan i förekommande fall anges.
SKA VARA PÅ SVENSKA ELLER ENGELSKA.

protocol-v1.3.0-2024-11-15.pdf
2.13MB

CV för ansvarig forskare

Bifoga CV för ansvarig forskare.
I undantagsfall kan icke disputerad forskare godtas om annan medverkande disputerad forskare uttalat att forskningen sker under aktivt överinseende av denne. Uttalandet intygas vid signering av disputerad forskare. CV för den disputerade ska även bifogas.
SKA VARA PÅ SVENSKA ELLER ENGELSKA.

cv.pdf
25.4KB

Signaturer

Signatur behörig företrädare

Signatur-behorig-foretradare.pdf
24.88KB

Signatur ansvarig forskare

Signatur-huvudansvarig-forskare.pdf
24.36KB

Beslut och handlingar från Etikprövningsmyndigheten

Beslutsbrev och andra handlingar från Etikprövningsmyndigheten i relation till denna ansökan

2024-07547-01_Avgiftsavisering.pdf
34.37KB

2024-07547-01_Ansokan_Godkand.pdf
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CLINICAL TRIAL PROTOCOL

ADVANCE TRAUMA

Effects of Advanced Trauma Life Support® Training Compared to Standard Care on Adult Trauma Patient Outcomes: A Cluster Randomised Trial

Version 1.3.0, 2024-11-15

Table of contents

1 Administrative information

1.1 Changelog

Version	Date	Details
1.3.0	2024-11-15	• Updated names of events in the table of procedures • Added new references • Added nested staircase design for measuring adherence, quality of life, disability and return to work • Updated small sample correction to be based on best available evidence closer to the time of analysis • Added contributors • Removed reassessment of the sample size calculation from the interim analysis • Revised details on measuring ATLS adherence
1.2.0	2024-08-26	• Added details on measuring ATLS adherence • Clarified the section describing the consent process • Fixed minor issues with how the variables were listed • Indicated non-routinely recorded data in the list of variables • Added Administrative information section with contributors • Added CTRI registration number
1.1.0	2024-05-09	Updated the primary outcome to in-hospital mortality and spelling corrections. The primary outcome was updated following a voting procedure in the Trial Management Group.

1.2 Study identifiers

- ClinicalTrials.gov identifier: NCT06321419
- Clinical Trials Registry - India identifier: CTRI/2024/07/071336

1.3 Contributors

The following have contributed to the design and implementation of the trial:

Name and ORCID	Affiliation	Role
Martin Gerdin Wärnberg	Karolinska Institutet, Stockholm, Sweden	Principal Investigator, TMG chair and TT member
Girish D Bakhshi	Grant Govt. Medical College & Sir J. J. Group of Hospitals, Mumbai, India	TMG member
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Abhinav Bassi	The George Institute for Global Health, New Delhi, India	TMG and TT member
Johanna Berg	Karolinska Institutet, Stockholm, Sweden	TMG member
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Name and ORCID	Affiliation	Role
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Abbreviations: TMG, Trial Management Group; TT, Trial Team.

2 Synopsis

Title Effects of Advanced Trauma Life Support® Training Compared to Standard Care on Adult Trauma Patient Outcomes: A Cluster Randomised Trial

Rationale Trauma is a massive global health issue. Many training programmes have been developed to help physicians in the initial management of trauma patients. Among these programmes, Advanced Trauma Life Support® (ATLS®) is the most popular, having trained over one million physicians worldwide. Despite its widespread use, there are no controlled trials showing that ATLS® improves patient outcomes. Multiple systematic reviews emphasise the need for such trials.

Aim To compare the effects of ATLS® training with standard care on outcomes in adult trauma patients.

Primary Outcome In-hospital mortality within 30 days of arrival at the emergency department.

Trial Design Batched stepped-wedge cluster randomised trial in India.

Trial Population Adult trauma patients presenting to the emergency department of a participating hospital.

Sample Size 30 clusters and 4320 patients.

Eligibility Criteria

Hospitals are secondary or tertiary hospitals in India that admit or refer/transfer for admission at least 400 patients with trauma per year.

Clusters are one or more units of physicians providing initial trauma care in the emergency department of tertiary hospitals in India.

Patients participants are adult trauma patients who presents to the emergency department of participating hospitals and are admitted or transferred for admission.

Intervention The intervention will be ATLS® training, a proprietary 2.5 day course teaching a standardised approach to trauma patient care using the concepts of a primary and secondary survey. Physicians will be trained in an accredited ATLS® training facility in India.

Ethical Considerations We will use an opt-out consent approach for collection of routinely recorded data. We will obtain informed consent for collection of non-routinely recorded data, such as quality of life and disability outcomes. Patients who are unconscious or lack a legally authorized representative will be included under a waiver of informed consent. Note that consent here refers to consent to data collection.

Trial Period November 2024, to October 2029

3 Background and rationale

Each year, 4.3 million people die from trauma[1]. Among people aged 10-24 and 25-49 years trauma is the largest cause of disability adjusted life years[2]. Most deaths from trauma occur within the first 24-48 hours[3]. Traumatic brain injury and exsanguination are the most common causes of trauma deaths[4,5]. Most preventable trauma deaths are caused by clinical judgement errors during initial resuscitation or early care including airway management and haemorrhage control, even though the deaths occur later during the hospital stay[4,6].

Several trauma life support training programmes have been developed to improve the early management of patients in the hospital by providing a structured framework for assessment and treatment[7–11]. The proprietary Advanced Trauma Life Support® (ATLS®) is the most established trauma life support training programme and more than one million physicians in over 80 countries have been trained in the programme since the first course in 1978[12]. In the US and many other countries training in ATLS® is virtually mandatory for trauma care physicians[13]. Uptake in low- and middle income countries (LMIC) has been slow, potentially due to high costs[9].

There are three randomised studies showing that ATLS® improves knowledge and clinical skills[14–16], but there are no randomised controlled trials or high-quality quasi-experimental trials indicating that ATLS® improves patient outcomes[7,8,10,11,17]. We conducted an updated systematic review (unpublished), and estimated a pooled risk ratio of 0.82 (95% CI 0.60; 1.11) from ten heterogeneous (I^2 0.91) observational studies on the effect of ATLS on mortality (see Figure 1)[18–27].

We conducted a pilot cluster randomised controlled trial (ClinicalTrials.gov NCT05417243) between April 2022 and February 2023 as part of our network grant to assess the feasibility of a full scale trial. We published the protocol for this pilot study[28]. Our pilot study enrolled 376 patients from seven hospitals across India (unpublished data) and shows that it is feasible to conduct the proposed trial with a high percentage of patients consenting to out of hospital follow up (78%), low loss to follow-up rate (1%), and low missingness in key variables (mean 0.8%).

To involve patients and the public in the planning of this trial we conducted 19 semi-structured interviews with trauma patients, caregivers, and community representatives (unpublished data). The aim of these interviews was to understand their views on the trial and important outcomes and the interviews showed high acceptability of our research and emphasised the importance of better recovery before discharge and functional outcomes at and after discharge, including pain, mobility and self-care activities. The interviews also highlighted return to work as an important outcome.

3.1 Updated systematic review

We performed a systematic literature search in the Medline, Embase, Cochrane, Web of Science, CINAHL and Google Scholar databases (PROSPERO ID CRD42022373977). The last search was conducted on November 11, 2022. We developed the search strategy in Medline (Ovid) in collaboration with librarians at the Karolinska Institutet University Library. We limited the search to English language articles, searched all databases from inception, and screened a total of 7896 records. We used a random effects model to pool estimates across studies.

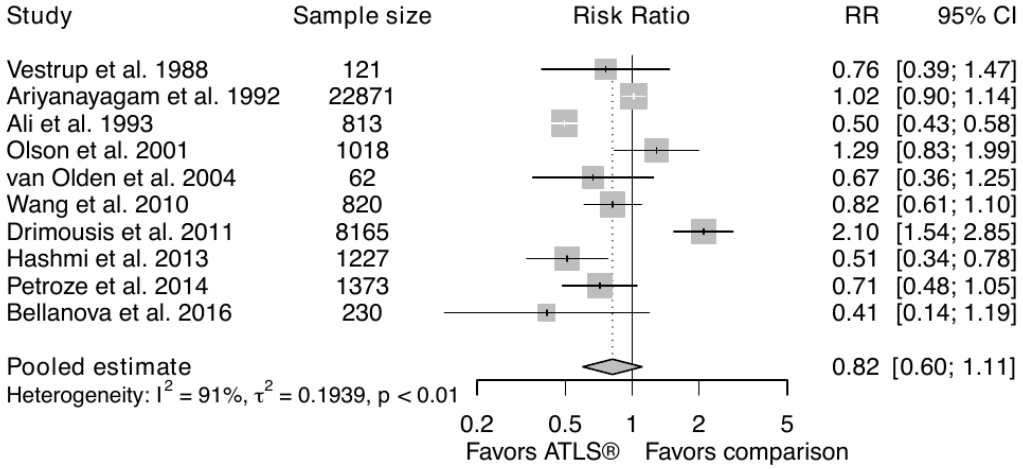

Figure 1: Summary of the updated system review. The forest plot shows the effect of ATLS on mortality. Abbreviations: RR, risk ratio; CI, confidence interval; ATLS, Advanced Trauma Life Support; I^2, heterogeneity.

4 Benefit-risk evaluation

The direct risks includes integrity violations and data leakage. We will mitigate these risks by employing rigorous data collection and storage mechanisms. The procedures that we will use to collect data will be direct observation of care, routine physical examinations, questionnaires, and extraction of already collected data from patient records, which are often seen as involving only minimal risk.

The long-term risks of the research and the risk that the research will be used in detrimental ways are minimal. Our trial will assess the effect of Advanced Trauma Life Support® (ATLS®) on patient outcomes. Training in ATLS® is standard in many health

care systems and it is unlikely that training physicians in this programme induces any harm to participants.

We consider these risks weighed up by the potential direct benefit for the participants in the intervention phase, if ATLS® is found to improve patient outcomes, and by the potential for improved care for the trauma patient population.

5 Trial aim

To compare the effects of ATLS® training with standard care on outcomes in adult trauma patients.

6 Regulatory approvals and trial registration

We will submit this trial to the Health Ministry Screening Committee at the Indian Council for Medical Research for their approval. We will apply for ethical approvals from each participating hospital, The George Institute for Global Health in India and the Swedish Ethical Review Authority. We will register this trial with Clinical Trials Registry-India and ClinicalTrials.gov.

7 Trial design and procedures

7.1 Overall trial design

We will conduct a batched stepped-wedge cluster randomised controlled trial (see Figure 2). The stepped-wedge trial is a uni-directional cross-over trial but the time point when clusters cross-over from standard care to the intervention is randomised[29]. Each cluster will be at least one unit of physicians performing initial resuscitation of trauma patients in the emergency department of tertiary hospitals in India. The number of units that we will train in each hospital will depend on the sizes of these units and the volumes of patients that they see. If more than one unit is trained in the same hospital these units will be considered one unit for the purpose of randomisation. We choose this approach for two reasons: 1) it will not be logistically or financially feasible to train all physician in a given hospital; and 2) we need to balance cluster size with the number of clusters. We will conduct this trial in India because physicians providing initial trauma care in India are so far not routinely trained in ATLS® or similar programmes.

We will roll out the interventions to 30 clusters over six batches, so there will be five clusters in each batch. The clusters in each batch will be randomised to one of five implementation sequences, with one hospital randomised to each implementation sequence.

All clusters will transition through three phases, first a standard care phase, then a one month transition phase during which the training is delivered, and finally an intervention phase, for a total of 13 months. The implementation sequence determines how long the phases of standard care and intervention are. Patient participants will be followed up for a total of three months.

7.2 Design justification

We use the cluster randomised design because the intervention cannot be randomised at the individual patient level. We use the stepped-wedge design for two reasons. First, this design is statistically more efficient than the parallel cluster design when the number of clusters is limited[30]. In this trial, the number of clusters is limited because of the costs associated with ATLS® training and the available slots for ATLS® training in India. Second, the stepped-wedge design is likely to enhance participation and engagement because all clusters receive the intervention. The batched stepped-wedge design further improves feasibility as it does not require all clusters to start at the same time, and it is robust to potential delays in cluster recruitment[31].

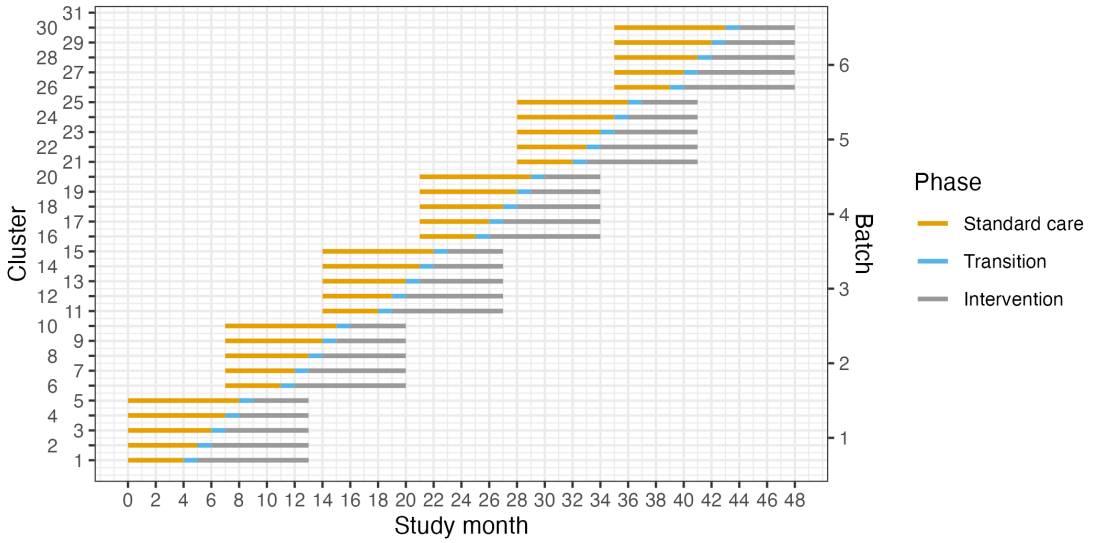

Figure 2: Trial design. Lines represent the duration of patient enrolment across clusters and phases. Clusters will be sequentially allocated to a batch based on when they enter the study. Within each batch clusters will then be randomised to an intervention implementation sequence.

7.3 Eligibility criteria

Our trial include eligibility criteria on three levels: hospitals, clusters and patient participants. We include eligibility on both the hospital and cluster level to facilitate the screening process.

7.4 Hospital selection

Hospitals will be secondary or tertiary hospitals providing trauma care in India. Hospital will be the unit of randomisation.

7.4.1 Inclusions criteria

Hospitals must meet the following criteria:

- admit or refer/transfer for admission at least 400 patients with trauma per year or 35 patients with trauma per month for at least the last six months;
- provide surgical and orthopaedic emergency services around the clock; and
- have at most 25% of physicians providing initial trauma care trained in a formalised trauma life support training programme, like ATLS® or Primary Trauma Care (PTC).

7.4.2 Exclusion criteria

Hospitals are excluded if they meet any of the following criteria:

- the hospital of the cluster implements a formalised trauma life support training programme [1] during the trial period; or
- the hospital of the cluster plan to implement or implements other major interventions[2] that affects trauma care during the trial period.

[1] These include but are not limited to the National Emergency Life Support (NELS) programme, the Basic Trauma Life Support (BTLS) programme, the Pre-Hospital Trauma Life Support (PHTLS) programme, the Trauma Nursing Core Course (TNCC) and the Advanced Trauma Care for Nurses (ATCN) programme.

[2] These include but are not limited to implementing of a trauma team approach, opening a trauma centre and implementing a trauma quality improvement programme.

7.4.3 Screening

The trial management group will compile a list of hospitals with potentially eligible clusters and reach out to them to assess their interest in participating in the trial. We will then screen hospitals for eligibility based on the criteria above, using a two-step procedure. First, we will approach hospitals to complete an initial hospital screening instrument (see Appendix Section 19.1). We will then discuss each eligible hospital individually in the Trial Management Group before deciding whether to include it in the trial. We have this discussion because we strive to include hospitals that to a large extent conducts primary resuscitation of trauma patients, rather than hospitals that primarily receives transferred patients from other hospitals, but this is difficult to formalise in the eligibility criteria. We will then perform a more in-depth interview with selected hospitals (See Appendix Section 19.2). To avoid excluding centres we will also discuss plans to implement other potentially competing interventions during the trial period, and take these plans into account when assigning clusters to batches. For example, we are aware of the ongoing implementation of the National Emergency Life Support (NELS) programme in India, and will therefore not include hospitals that plan to implement this programme during the trial period. All screening steps and decisions will be logged using REDCap[32,33].

7.5 Cluster selection

Clusters are one or more units of physicians providing initial trauma care in the emergency department of secondary or tertiary hospitals in India. These units already exist in the hospitals and rotate through the emergency department on specific days of the week.

7.5.1 Inclusion criteria

Clusters must meet the following criteria:

- admits or refers/transfers for admission at least 12 patients with trauma per month for at least the last six months; and
- no more than 25% of physicians providing initial trauma care trained in a formalised trauma life support training programme.

7.5.2 Screening

The screening of clusters is part of the hospital screening process.

7.6 Patient participants selection

Patient participants are adult trauma patients who presents to the emergency department of participating hospitals and are admitted or transferred for admission.

7.6.1 Inclusion criteria

Patients participants must meet the following criteria:

- age of at least 15 years;
- trauma occurred less than 48 hours before arrival at the hospital;
- present to the emergency department of participating hospitals, with a history of trauma defined as having any of the reasons listed in the International Classification of Diseases chapter XX as the reason for presenting;
- admitted, or died between arrival at the hospital and admission, or referred/transferred from the emergency department of a participating hospital to another hospital for admission; and
- managed by a participating cluster in the emergency department.

7.6.2 Exclusion criteria

Patients participants are excluded if they meet the following criteria:

- present with isolated limb injuries; or
- are directly admitted to a ward without being seen by a physician in the emergency department.

7.6.3 Screening

Clinical research coordinators will screen patient participants either as they arrive to the emergency department or using emergency department registers. The patients or their representatives will receive written information about the study before they are discharged, including about their right to opt out at any time before final analysis. Phone numbers for out of hospital follow up will be extracted from the emergency department registers, and will be securely held only by the clinical research coordinators at each sites.

7.6.4 Withdrawal criteria

Patient participants can choose to withdraw their consent for collection of non-routinely recorded data at any time before the final analysis. If they withdraw their consent for this data collection the clinical research coordinator will not collect any more of this data, which also means that no further follow-ups will be conducted. They can also choose to have the data already collected about them removed from the trial at any time before final analysis of the data. Withdrawal of consent or removal of data from the trial will not affect their care in any way. If the patient participant withdraws consent, follow-up of this participant will be performed according to the participating hospitals routine.

7.7 Procedures

Table 3 shows an overview of trial procedures before and during patient admission, and Table 4 shows an overview of trial follow-up procedures. Clinical research coordinators will follow up patients daily until discharge to capture injury information. They will also follow up patients at 24 hours, 30 days and 90 days after arrival to the emergency department to capture mortality outcomes, and at 30 days and 90 days after arrival to the emergency department to capture functional outcomes and return to work. If patient participants are discharged before any of these follow-up time points, clinical research coordinators will follow up patients by phone.

Table 3: Overview of trial procedures before and during patient admission

Procedure	Screening	Consenting	Initial assessment	In-hospital care
Eligibility criteria	√			
Study information[1]		√		
Informed consent[1]		√		
Baseline data collection			√	
Prehospital data collection			√	
ATLS adherence[2]			√	
ED data collection[3]			√	
Hospital data collection				√
Surgery data collection				√
Imaging data collection				√
Transfusion data collection				√
Injury data collection				√
Mortality data collection				√
Assessment of safety events				√

[1]Clinical research coordinators will inform patient participants about the study, including that they are free to withdraw their data from the study at any time, and approach them for informed consent for collection of non-routinely recorded data in person or telephonically.
[2]ATLS adherence will be assessed by observing the care provided to a random sample of patient participants.
[3]Emergency Department

Table 4: Overview of trial follow-up procedures

Procedure	Within 7 days of discharge	30 days	90 days
Mortality data collection[1]	√	√	√
EQ-5D/WHODAS	√	√	√
Return to work		√	√
End of study			√

[1]Will be ascertained daily from when the patient participant arrive to hospital until they leave the hospital, are discharged or die.

7.8 Biological sampling procedures

This trial does not include biological sampling.

7.9 End of trial

The trial ends when the last patient participant has completed the last follow-up. The trial may be prematurely terminated if it this is necessary for safety reasons affecting the risk-benefit balance or if the recruitment of subjects cannot be met within reasonable time limits. If the trial is prematurely terminated or suspended, the investigator should immediately inform the subjects about this and ensure appropriate treatment and follow-up. Decisions on premature termination are taken by the joint Trial Steering and Data Monitoring Committee and Trial Management Group.

7.10 Intervention and control treatment

The intervention will be ATLS® training. The control will be standard care, meaning no formal trauma life support training. We will train the physicians that initially resuscitate and provide trauma care during the first hour after patient arrival at the emergency department. These physicians can be casualty medical officers, surgical residents, or emergency medicine residents, depending on the setup at each participating centre. The training will occur during the transition phase in each cluster. Our experience from our pilot study is that study sites adhere to the training slot alloted to them through the trial, so we judge the risk of clusters implementing ATLS® before their randomised implementation sequence as very low.

We will train the number units of physicians needed to reach the required patient sample size, but estimate that this will require training an average of ten physicians per hospital, which on average should be mean that we can train one to two units per hospital. This is possible because many hospitals in India organise physicians staffing their emergency departments in units, and the physicians in the same unit work together in the emergency

department on the same days of the week. We will therefore collect data only on the days when these units work. The units selected to constitute a cluster from each hospital will be a convenience sample out of all eligible units in those hospitals.

Advanced Trauma Life Support® (ATLS®)[12] is a proprietary 2.5 day course teaching a standardised approach to trauma patient care using the concepts of a primary and secondary survey. The programme was developed by the Committee of Trauma of the American College of Surgeons. The course includes intial treatment and resuscitation, triage and interfacility transfers. Leaning is based on practical scenario-driven skill stations, lectures and includes a final performance proficiency evaluation. Physicians will be trained in an accredited ATLS® training facility in India. We will assess adherence to ATLS principles before and after implementing ATLS training.

Standard care varies across hospitals in India, but trauma patients are initially managed by casualty medical officers, surgical residents, or emergency medicine residents. They are mainly first- or second-year residents who resuscitate patients, perform interventions and refer patients for imaging or other investigations. Compared with other settings where a trauma team approach is adopted, nurses and other healthcare professionals are only involved to a limited extent during the initial management.

7.10.1 Description of investigational medicinal products

This trial does not include any investigational medicinal products.

7.10.2 Auxiliary medicinal products

This trial does not include any auxiliary medicinal products.

7.10.3 Concomitant use of other medications or treatments

Other than implementing another formalised trauma life support training programme or other major interventions to change the care of trauma patients as specified in the exclusion criteria, concomitant use of other medications and treatments may be provided at the discretion of the investigators and will not be considered an exclusion criterion.

7.11 Randomisation

We will assign clusters to batches as they are found to be eligible and receive ethical approval. Batches will include clusters from hospitals in different regions to optimize trial

logistics. We will randomise the clusters alloted to each batch to the different intervention implementation sequences within that batch[3]. We will balance the randomisation within each batch on cluster size, defined as monthly volume of eligible patient participants, using covariate constrained randomisation. The cluster sizes are expected to vary between 12 and 20 patients per month, based on our previous experiences. We will conceal the randomisation order for as long as it is logistically possible, considering that arrangements for sending physicians to ATLS® training need to be made in advance.

7.12 Blinding

It is not possible to blind a stepped-wedge trial, because all clusters receive the intervention.

7.13 Treatment after trial end

When the trial ends, the intervention will have been implemented in all clusters.

7.14 Outcomes

7.14.1 Primary outcome

The primary outcome will be in-hospital mortality within 30 days of arrival at the emergency department. Clinical research coordinators will extract information on death from patient hospital records. If the patient has been transferred to another hospital, the clinical research coordinators will collect data on this outcome by calling the patient or a patient representative, or by contacting the hospital to which the patient was transferred. Data on this outcome will be collected continuously during the trial.

7.14.2 Secondary outcomes

- All cause mortality within 24 hours, 30 days and three months of arrival at the emergency department. Data on this outcome will be collected in the same way as for the primary outcome.
- Length of emergency department stay. Data on this outcome will be collected from patient hospital records.
- Length of hospital stay. Data on this outcome will be collected from patient hospital records.
- Intensive care unit admission. Data on this outcome will be collected from patient hospital records.

[3]Randomisation will be done using bespoke code from previous trials.

- Length of intensive care unit stay. Data on this outcome will be collected from patient hospital records.
- Adherence to ATLS® principles during initial patient resuscitation, up to one hour after the physician has first seen the patient. This assessment will be done using a 14 item checklist covering the key steps of the ATLS® primary survey, which was modelled based on previous work on ATLS® adherence[34]. We will consider completion of all 14 steps as 100% adherence. The clinical research coordinators collecting the data will be trained by the trial team to do this, prior to the start of the trial. We will collect this data by observing the care of a random sample of patients. The sampling will be designed as a nested staircase design.
- Quality of life within seven days of discharge, and at 30 days and three months of arrival at the emergency department, measured by the official and validated translations of the EQ5D3L. Data on this outcome will be collected in person if the patient is still in hospital, or by phone if the patient has been discharged. We will collect this data using a nested staircase design.
- Disability within seven days of discharge, and at 30 days and three months of arrival at the emergency department, assessed using the WHO Disability Assessment Schedule 2.0 (WHODAS 2.0). Data on this outcome will be collected in person if the patient is still in hospital, or by phone if the patient has been discharged. This data will also be collected using a nested staircase design.
- Return to work at 30 days and three months after arrival at the emergency department. Data on this outcome will be collected in person if the patient is still in hospital, or by phone if the patient has been discharged. This data will also be collected using a nested staircase design.

7.15 Handling of adverse and safety events

7.15.1 Definitions

7.15.1.1 Adverse event

Any untoward medical occurrence in a clinical trial subject and, which does not necessarily have a causal relationship with the treatment, can be an unfavorable and unintended sign (including an abnormal laboratory discovery), symptom or disease temporally associated with the inclusion in the trial, whether or not related to the trial.

7.15.1.2 Serious adverse event

Any untoward medical occurrence in a trial participant that:

- leads to death
- is life-threatening
- requires inpatient hospitalization or prolongation of existing hospitalization

- results in persistent or significant disability or incapacity
- results in a congenital anomaly/malformation

7.15.1.3 Safety event

Any unexpected serious complication that might occur as a consequence of the trial and that are not part of the natural history of trauma.

7.15.2 Reporting and assessment of adverse and safety events

In alignment with other current trials including critically ill patients[35], we will not collect adverse events or serious adverse events, because many of these events are expected in this patient population and we already collect many of these events, for example mortality, as part of our outcomes.

We will only report safety events, if they are life-threatening, prolong hospitalisation or result in meaningful harm to the participant. We cannot pre-define a comprehensive list of events that can be considered safety events, but will actively assess the presence of the following safety events:

- Prolonged mechanical ventilation (> 7 days)
- Initiation of renal replacement therapy
- Prolonged (> 2 days) or renewed (restart after at least 2 days without) use of vasopressors such as norepinephrine or vasopressin

These events are considered safety events because they suggest pulmonary, renal, septic or bleeding complications and an increase in their occurrence following ATLS® training could indicate that the intervention is harmful. These events therefore need to be tracked during the standard care phase as well as the intervention phase, but will only be considered indicative of harm related to the intervention if they occur more often during the intervention phase than during the standard care phase.

We will also report any other safety events that we identify during the trial, and the reporting of such will have to be based on the intuition of the clinical research coordinators and local investigators. Examples of such safety events could include missed injuries or missed investigations, which could be suspected if certain injuries or investigations were identified or conducted more often during the standard care phase than during the intervention phase.

All safety events will be recorded in the Case Record Form (CRF) and reported to the trial management team within 24 hours of its occurrence. The trial management team will then assess if the event can be considered related to the trial or the intervention within 24 hours of it being reported. Events that are considered probably related will be reported immediately to the joint Trial Steering and Data Monitoring Committee.

7.15.3 Follow up of safety events

All safety events should be followed up by the local investigator until they are fully evaluated.

7.16 Statistics

7.16.1 General principles

We will conduct all analysis by modified intention to treat. Clusters and observations within clusters will be considered exposed to the intervention after the date at which the cluster was scheduled to transition. All data will be included with the exception of the transition phases. We will not adjust for multiplicity of analyses because none of the secondary outcomes will be singularly more important. However, all secondary outcomes will be interpreted with due consideration for how all are affected by the intervention without putting any undue emphasis on a single outcome that might be statistically significant but where all others appear to have remained unchanged.

We will use a two-sided significance level of 5% and estimate 95% confidence intervals. The primary subgroup analyses will be based on geographical region because demonstrating the consistency of any effect across multiple regions will enhance the generalisibility of the results[4]. Additional subgroup analyses will include age across the groups older adolescents (15-19 years), young adults (20-24 years), adults (25-59 years), and older adults (60 years and older)[36]; sex; and the clinical cohorts blunt multisytem trauma, penetrating trauma, and severe isolated traumatic brain injury.

7.16.2 Analysis models

There are a number of requirements for the analysis model. Firstly, all analysis will consider the clustered nature of the design. Secondly, as the trial has only 30 clusters, it will be essential that the model allows for a correction due to the small number of clusters. Thirdly, as the design is a stepped-wedge study, we will adjust for temporal confounding using categorical effects for period of the study (month). Full details on how each of these will be undertaken, with justification is provided below[37].

For binary outcomes, a mixed effects binomial regression with a logit link will be used to estimate the odds ratio; and a binomial model with identity link used to estimate the risk difference. These models will be fitted using residual pseudo-likelihood estimation based on linearization with subject-specific expansion (RSPL). If the binomial model with the identity link does not converge then only a odds ratio will be reported.

[4]**Note:** Batches will not be based on regions because it will be logistically more feasible to include clusters from different regions in each batch.

We will include fixed effects for period and a fixed effect for intervention exposure. The primary analysis will allow for clustering by as a random cluster and random cluster by period effect. To correct the potential inflation of the type I error rate due to small number of clusters, a correction for a small number of clusters will be applied, but the correction that will be selected will be based on the best available evidence available closer to the time, and it may differ for the outcomes collected via the complete and incomplete designs. In a sensitivity analysis we will explore if models with more complicated correlation structures are a better fit to the data. These models are not being used as our primary analysis models as there is limited understanding as to when such models will converge and how to choose between the various different correlation structures which might be plausible.

To this end we will additionally fit generalised linear mixed models (with same link functions and fixed effects as described above) to include a discrete time decay correlation structure including a random cluster effect with auto-regressive structure (AR(1)). To allow for the randomisation by batches, a different secular trend will be included for each batch (interaction between batch and period). For continuous, count and prevalence outcomes similar model-based approaches will be used but with appropriate links and distribution functions, using transformations where appropriate.

7.16.3 Additional sensitivity analyses

To additionally explore if the fixed period effect is both parsimonious and adequate to represent the extent of any underlying secular trend, we will model the time effect using a spline function. Models will also be extended to include random cluster by intervention effects (with a non-zero covariance term) to examine if results are sensitive to the assumption of no intervention by cluster interaction. Models will also be extended to include an interaction between treatment and number of periods since first treated, to examine if there is any indication of a relationship between duration of exposure to the intervention and outcomes.

This will allow us to different lag effects (whereby it takes time for the intervention to become embedded within the culture before its impact can properly start to be realised); as well as weaning effects (whereby the effect of the intervention starts to decrease – or fade). This type of analysis attempts to disentangle how some clusters end up having a long exposure to the intervention and others have a much shorter exposure time. A fully adjusted covariate analysis will additionally adjust for a set of pre-specified individual-level covariates of known prognostic importance.

7.16.4 Estimation and reporting of within cluster correlations

We will report time adjusted within-cluster correlations for all outcomes with 95% confidence intervals. We will report correlations from the different assumed correlation

structures (so we will report intra-cluster correlations (ICC); within and between-period correlations; and within-period correlations and exponential decay). As well as reporting correlations we will additionally report all variance components. For all outcomes we will report correlations on the latent scale (i.e. proportions scale for binary outcomes) as is appropriate to inform future sample size calculations.

7.16.5 Sample size calculations

With 30 clusters across 6 batches and a total sample size of 4320 our study has ~90% power across different combinations of cluster autocorrelations (CAC) and intra-cluster correlations (ICC) to detect a reduction in the primary outcome of in-hospital mortality within 30 days from 20% under standard care to 15% after ATLS® training (see Figure 3). This effect is a conservative estimate and the reduction equals a risk ratio of 0.75, which would be clinically important while also being consistent with our pilot study and updated systematic review. We allowed for the clustered design and assumed an ICC of 0.02, but considered sensitivity across the range 0.01-0.05[38,39], and a CAC of 0.9 but considered sensitivity across the range 0.8-1.0, based on our pilot study and current guidance[40–42]. We included the CAC to allow for variation in clustering over time. We assume that each cluster will contribute approximately 12 observations per month to the analysis, based on our previous work.

7.16.6 Interim analysis

There will be one interim analyses after half of the batches have completed the trial. The interim analyses will be assessed by the joint Trial Steering and Data Monitoring Committee. The purposes of this interim analysis will be to:

- assess the trial's feasibility and recommend stopping the trial if the trial is not feasible, for example if hospitals fail to adhere to the randomisation schedule or if there are substantial missing data in outcomes;
- compare characteristics across intervention conditions to monitor for differential recruitment/ascertainment between intervention and control.

7.17 Quality control and quality assurance

The George Institute for Global Health - India will ensure proper conduct of the trial through quality control measures including on-site training of personnel, standard operating procedures, ongoing quality metrics assessment, review of missing data and outliers, and round-the-clock availability of coordinating center personnel and Principal Investigators. The trial will strictly follow ICH GCP principles, Indian regulations, and George Institute procedures. The trial operations staff from the George Institute India will train local investigators, and trial site staff, before the trial, with continuous documentation

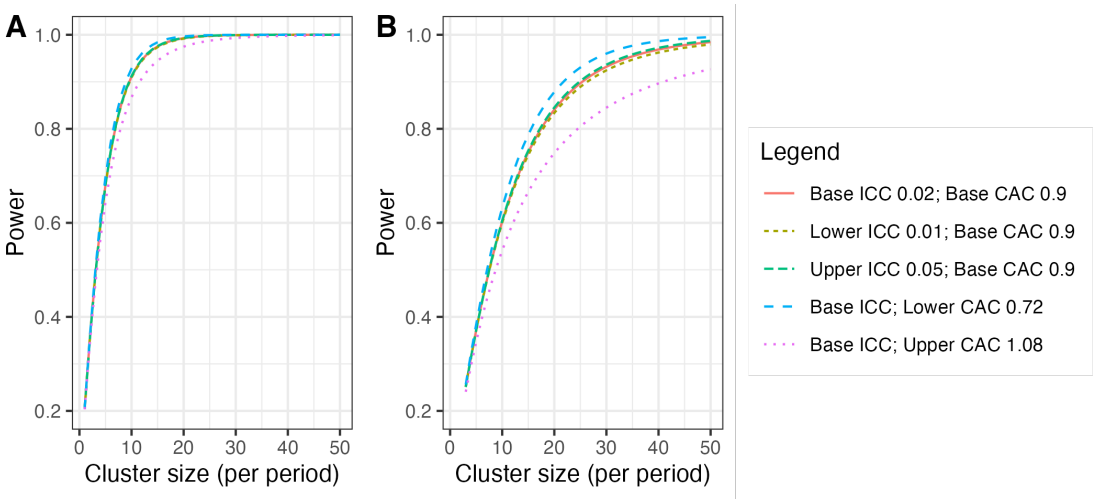

Figure 3: Power curves for different combinations of cluster autocorrelations (CAC) and intra-cluster correlations (ICC). **A)** Shows power curves assuming a reduction in the primary outcome of in-hospital mortality within 30 days from 20% under standard care to 15% after ATLS® training. **B)** Shows power curves assuming a reduction in the primary outcome from 10% under standard care to 7.5% after ATLS® training. Under this scenario, we would need to increase the sample size per month to around 30 observations to achieve 90% powere under most combinations of CAC and ICC.

in the site master file. All documentation will be stored securely and retained according to regulatory requirements.

7.18 Quality assurance and oversight

The Trial Management Group and Trial Team, comprising key project leaders and managers, will play a pivotal role in ensuring the highest standards of quality assurance and effective sponsor oversight throughout the trial. These groups will be responsible for facilitating consistent communication, maintaining fidelity in study implementation, and overseeing the quality of data collection.

To achieve these objectives, the groups will implement a comprehensive communication plan and provide extensive training to site personnel. The training will cover not only the study protocol but also practical aspects of various systems, supplemented by both written and electronic materials designed to educate study and clinical emergency staff.

The trial's quality assurance systems will be meticulously designed based on a thorough risk analysis. A key component of our quality assurance strategy will include the development and implementation of detailed operational manuals and regular meetings. These tools and interactions will ensure that all trial personnel will be used to uphold the trial's quality standards.

Central to our oversight approach will be a comprehensive monitoring and auditing plan. This plan will be tailored based on the identified risks associated with the trial. Through these comprehensive measures, the trial management group, in conjunction with the hospital staff, will ensure that the trial is conducted with the utmost rigor, adhering to the highest standards of quality assurance and effective sponsor oversight.

7.19 Monitoring

We will implement a multi-tiered monitoring strategy, including centralized data consistency checks, statistical monitoring, and selective on-site evaluations. Key integrity measures include source data verification, data entry validation, and regular audits. Any protocol deviations will be thoroughly documented, with serious breaches promptly addressed to ensure data integrity. Monitors from coordinating centres will assist investigators in maintaining high ethical, scientific, technical, and regulatory quality. Monitoring visits will review protocol adherence, participant recruitment, adverse event reporting, compliance with study procedures, and regulatory adherence. Regular remote monitoring of the web-based database will be conducted to ensure data integrity, using validation and consistency rules and regular data cleaning. The Trial Team and Trial Management Group will monitor baseline characteristics, opt-in consent rates and differential opt-in consent rates across trial arms, follow-up rates, CRF return and completeness rates, and safety data.

8 Deviations, serious breaches and other reporting obligations

The responsible investigator shall, without delay, report to the sponsor any serious breaches and deviations from the trial protocol, ICH-GCP and other regulations that significantly and directly affect, or with high likelihood could affect, the subjects' safety and integrity or the reliability and robustness of the data generated in the trial. The sponsor should assess the suspected serious breach and the consequences of deviations that have occurred. Minor deviations that do not affect subjects' integrity or safety, nor significantly affect the trial's scientific value, are documented in the trial documentation of the principal investigator and the sponsor and appropriate measures shall be taken. The deviations must be recorded in the clinical trial report.

9 Audits and inspections

Authorized representatives for the sponsor and Competent Authorities (CA) may carry out audits or inspections at the trial site, including source data verification. The investigator must ensure that all source documents are available for audits and inspections. The purpose of an audit or inspection is to systematically and independently review all trial-related activities and documents, to determine whether these activities were performed, registered, analyzed and reported correctly according to protocol, ICH- GCP and applicable regulations.

10 Ethics

10.1 Compliance to the protocol, ICH-GCP and regulations

The trial will be performed in compliance with this clinical trial protocol, the Declaration of Helsinki, ICH-GCP (Good Clinical Practice), and current national regulations governing this clinical trial. This is to ensure the safety and integrity of the trial subjects as well as the quality of the data collected.

10.2 Ethical review of the trial

The final protocol will be submitted for ethical review at all participating hospitals, where possible, as well as the The George Institute for Global Health in India and Swedish Ethical Review Atuhortiy.

10.3 Procedure for obtaining consent

In this trial, consent refers to data collection, as patients cannot opt out of the intervention. This is because the intervention is implemented at the cluster level, involving training physicians in ATLS®. It is unreasonable to expect these physicians to temporarily disregard their training. Patient participants will be included in this trial under the following modes of consent:

- Opt out consent for **routinely recorded data and measurement of adherence to ATLS® principles**. Consent for the collection of routinely recorded data, either through interviews or by extracting information from medical records, as well as for the measurement of adherence to ATLS® principles, will be presumed unless explicitly declined. This approach is justified because the trial is considered to pose minimal risk and because data collection will be non-invasive. Additionally, obtaining consent specifically for the measurement of adherence to ATLS® principles could interfere with the provision of care and cause undue stress for the patient and their representatives. Patients, or their legally authorized representatives, will be provided with written information about the study upon their arrival at the hospital. The variables assumed to be routinely recorded are listed in Section 13.2.
- Opt in consent and assent for **non-routinely recorded data**. Informed consent for non-routinely recorded data will be actively sought from patient participants or their legally authorized representative. For participants who are between 15 and 18 years of age we will obtain both the assent of the participant as well as the consent of their guardian or legally authorized representative. The clinical research coordinators will approach patient participants and their representatives after admission. The consent and assent will be written for patient participants who are admitted to the hospital and verbal for participants who are transferred or discharged before the clinical research coordinators have had an opportunity to approach them. The verbal consent will be audio recorded.
- Waiver of informed consent for patients who are unconscious or otherwise unable to provide consent and do not have a legally authorized representative. This group represents the most severly injured patients and they have to be included to make the trial representative of the entire population of trauma patients. Patients participants who regain consciousness will be informed about the study and asked for consent for collection of non-routinely recorded data.

10.4 Data protection

All data will be handled according to the Indian Council of Medical Research's guidelines and standard operating procedures of the George Institute for Global Health India on data security and protection. Trial data will be shared via the trial electronic CRF (eCRF) throughout the trial. The eCRF will be accessible via VPN with a two-factor

authentication and the data will be held on a secure server. All investigators and trial site staff involved in this trial must comply with the requirements of the ICMR Guidelines on data security and protection. The participant information sheet provided to participants, will inform them how:

- the trial data will be collected, used and disclosed;
- how trial data are stored to maintain confidentiality in accordance with national data legislation; and
- for verification of the data, representatives delegated by the sponsor, as well as relevant authorities, may require access to parts of medical records or trial records that are relevant to the trial, including the patient participant's medical history.

11 Insurances

The George Institute for Global Health, India is responsible for ensuring that any insurance cover required to cover the set-up, management and conduct of the study in India has been obtained. The George Institute for Global Health, India is also responsible for ensuring that India Sites have been obtained and/or will obtain insurance prior to the opening of the study in India and shall be maintained for the duration of the study and for an appropriate period thereafter. This includes being responsible for ensuring that there is appropriate insurance for the duration of the study to cover against claims for compensation by participants arising out of their participation in the trial in India. Compensation in case of injury or death will be provided by the George Institute for Global Health, India according to the regulations outlined in rules 39, 40 and 42 of the New Drugs and Clinical Rules (2019). x

12 Substantial changes to the trial

Substantial changes to the signed clinical trial protocol are only possible through approved protocol amendments and by agreement between the sponsor and the principal investigator.

13 Collection, handling, and archiving of data

Clinical research coordinators will collect data using a paper based CRF (see Appendix Section 19.3), which is then transferred to an eCRF. All trial data in the CRF must be extracted from and be consistent with the relevant source documents. The eCRF will be accessible to trial coordinators, data managers, the Investigators, Clinical Trial Monitors, Auditors, and Inspectors as required. All data will be registered, managed, and stored in a manner that enables correct reporting, interpretation, and verification. The complete

Trial Master File, as well as source documents, will be archived for at least 10 years after the trial is completed. Source data in the medical records system are stored and archived in accordance with national regulations. Metadata will be publicly accessible via a persistent DOI, and anonymised data will be released upon project completion. A detailed data management plan is available here https://doi.org/10.5281/zenodo.7748764.

13.1 Source data

The source data for each variable is given in Section 13.2. Whenever medical records are the source data, this includes imaging and lab reports. Whenever an interview is given as the source, the CRF will constitute the source data, as this is where the responses to questions will be recorded. The local investigator must keep source documents for each patient participant in the trial. A document describing what has been classified as source data in the trial (source data reference document) will be included in the Investigator Site File (ISF). The investigator must ensure that all source documents are accessible for monitoring and other quality control activities. Source data is further defined before trial start at each individual site and can, in cases where source data is not registered in another document, consist of the CRF. This should be decided in consultation with the monitor and clearly stated in the source data reference document. Access to trial-related documentation, such as patient participants' medical records, CRFs, other source data and other trial documentation will be provided for monitoring and auditing purposes. Access will also be granted in the context of regulatory inspections.

13.2 Variables

13.2.1 Screening

- **Screening ID**
- **1. Date of screening**
- **2. Date of data entry**
- **1. Is the patient at least 15 years old?** Source: Medical record or interview
    1. Yes
    2. No
- **2. Did the patient present with a history of trauma defined as having any of the reasons listed in the International Classification of Diseases chapter XX as the reason for presenting? Please see https://icd.who.int/browse10/2019/en#/XX for a complete list of ICD-10 codes** Source: Medical record or interview

1. Yes
2. No

- **3. Did the trauma occur less than 48 hours before arrival to the hospital?** Source: Medical record or interview

  1. Yes
  2. No

- **4. Was the patient admitted?** Source: Medical record

  1. Yes
  2. No

- **5. Did the patient die after arrival but before admission?** Source: Medical record

  1. Yes
  2. No

- **6. Was the patient transferred to another hospital for admission?** Source: Medical record

  1. Yes
  2. No

- **1. Did the patient present with isolated limb injury?** Source: Medical record

  1. Yes
  2. No

- **2. Was the patient directly admitted to a ward without being seen by a physician in the emergency department?** Source: Medical record

  1. Yes
  2. No

13.2.2 Consent

- **1. Is this patient included under the waiver of informed consent because the patient is unconscious or otherwise unable to provide consent and do not have a legally acceptable representative?**

  1. Yes
  2. No

- **1. Did the participant/ or legally acceptable representative (LAR) provided consent for collection of non-routinely recorded data**

    1. Yes
    2. No

- **2. Who gave consent for collection of non-routinely recorded data?**

    1. Patient participant
    2. Legally acceptable representative

- **3. Relation of LAR with the Participant**
- **4. Why was Legally acceptable representative (LAR) approached for consent for collection of non-routinely recorded data?**

    1. The participant is incapacitated because of the trauma
    2. The participant is younger than 18 years

- **5. Date when participant or legally acceptable representative (LAR) gave consent for collection of non-routinely recorded data?**
- **6. How did the participant or legally acceptable representative (LAR) consent for collection of non-routinely recorded data?**

    1. In writing
    2. Verbally

- **7. Date when the participant was reconsented?**
- **1. Did the minor give assent for collection of non-routinely recorded data?**

    1. Yes
    2. No

- **2. Date when the minor gave assent for collection of non-routinely recorded data.**
- **3. In case the minor refused to participate, date when minor refused**
- **1. Is the participant or LAR wants to opt out from study?**

    1. Yes
    2. No

- **2. Who opted-out of the routinely recorded data (in-hospital)?**

    1. Patient participant

2. Legally acceptable representative (LAR)

- **3. Date when participant or legally acceptable representative (LAR) opted-out.**
- **4. Did the participant or legally acceptable representative (LAR) suggested to delete all the previously recorded data?**

1. Yes
2. No

13.2.3 Consent withdrawn

- **1. Does the participant or legally acceptable representative (LAR) want to withdraw the consent?**

1. Yes
2. No

- **2. Date of consent withdrawal for follow-up data collection.**
- **3. Procedure(s) for which consent has been withdrawn**

1. Data collection prior to withdrawal
2. All data collection after withdrawal
3. Both

13.2.4 Baseline

- **1. Age in years** Source: Medical record of interview
- **2. Sex** Source: Medical record of interview

1. Female
2. Male
3. Other
4. Not known

- **3. Current marital status** Requires opt-in consent, not routinely recorded. Source: Interview

1. Never married
2. Currently married
3. Separated
4. Divorced
5. Widowed

6. Cohabiting
7. Not known

- **4. Education level** Requires opt-in consent, not routinely recorded. Source: Interview

1. Not attended school
2. Primary school
3. Secondary school
4. Higher secondary school
5. Graduate
6. Post graduate and above
7. Other
8. Not known

- **5. If other, please specify** Requires opt-in consent, not routinely recorded. Source: Interview
- **6. Main work status** Requires opt-in consent, not routinely recorded. Source: Interview

1. Paid work, such as daily wage earner, teacher, factory worker and government employee
2. Self-employed, such as own your business or farming
3. Non-paid work, such as volunteer or charity
4. Student
5. Keeping house/homemaker
6. Retired
7. Unemployed (health reasons)
8. Unemployed (other reasons)
9. Other
10. No income
11. Not known

- **7. If other, please specify** Requires opt-in consent, not routinely recorded. Source: Interview
- **8. Income level in INR per month** Requires opt-in consent, not routinely recorded. Source: Interview

1. Below 10,000
2. 10,001-20,000
3. 20,001-30,000
4. 30,001-50,000
5. 50,001-80,000
6. 80,001-1,00,000

7. Above 1,00,000
8. Not known

- **9. Mechanism of injury** Coded using ICD 10. Source: Medical record
- **10. Clinical Frailty Scale** Source: Medical record or treating physician

1. 1. Very fit
2. 2. Fit
3. 3. Managing well
4. 4. Living with very mild frailty
5. 5. Living with mild frailty
6. 6. Living with moderate frailty
7. 7. Living with severe frailty
8. 8. Living with very severe frailty
9. 9. Terminally ill
10. Not known

- **11. Comorbidities (Charlson Comorbidity Index)** Source: Medical record, treating physician or interview

1. Myocardial infarction
2. Congestive heart failure
3. Peripheral vascular disease
4. Cerebrovascular disease
5. Dementia
6. Chronic pulmonary disease
7. Rheumatologic disease
8. Peptic ulcer disease
9. Liver disease
10. Diabetes
11. Hemiplegia or paraplegia
12. Renal disease
13. Malignancy
14. Leukemia
15. Lymphoma
16. AIDS
17. Not known
18. None

- **12. Severity of liver disease** Source: Medical record, treating physician or interview

    1. Mild
    2. Moderate or severe
    3. Not known

- **13. Severity of diabetes** Source: Medical record, treating physician or interview

    1. Controlled
    2. Uncontrolled
    3. Not known

- **14. Severity of malignancy** Source: Medical record, treating physician or interview

    1. Localized
    2. Metastatic tumor
    3. Not known

13.2.5 Prehospital

- **1. Date and time of injury** Source: Medical record of interview
- **2. Mode of transport to the participating hospital** Source: Medical record of interview

    1. Ambulance
    2. Police
    3. Private vehicle
    4. Walking
    5. Others
    6. Not known

- **3. If other, please specify** Source: Medical record of interview
- **4. Referred or transferred to the participating hospital from another hospital** Source: Medical record of interview

    1. Yes
    2. No
    3. Not known

13.2.6 ATLS adherence

- **1. Airway patency checked** Source: Observation
    1. Yes
    2. No
- **1. Chest wall palpated** Source: Observation
    1. Yes
    2. No
- **2. Breath sounds checked** Source: Observation
    1. Yes
    2. No
- **3. Respiratory rate measured** Source: Observation
    1. Yes
    2. No
- **4. Saturation (SpO2) measured** Source: Observation
    1. Yes
    2. No
- **1. Heart rate measured** Source: Observation
    1. Yes
    2. No
- **2. Blood pressure measured** Source: Observation
    1. Yes
    2. No
- **3. Abdomen palpated** Source: Observation
    1. Yes
    2. No
- **4. Thighs palpated** Source: Observation
    1. Yes
    2. No
- **5. IV access obtained** Source: Observation

1. Yes
2. No

- **1. GCS checked** Source: Observation

1. Yes
2. No

- **2. Pupils checked** Source: Observation

1. Yes
2. No

- **1. Patients exposed for assessment**

1. Yes
2. No

- **2. Temperature measured** Source: Observation

1. Yes
2. No

- **1. Which airway interventions were performed?** Source: Observation

1. None
2. Manual airway procedure such as chin lift or jaw thrust
3. Nasopharyngeal or Oropharyngeal airway inserted
4. Supraglottic airway device
5. Tracheal intubation
6. Surgical airway
7. Other
8. Not known

- **2. If other airway Interventions given, specify**
- **3. Were airway interventions performed while minimising c-spine movement?** Source: Observation

1. Yes
2. No
3. Not known

- **1. Which breathing interventions were performed?** Source: Observation

1. None
2. Oxygen applied
3. Intracostal drain placement

4. Other
5. Not done
6. Not known

- **2. If other breathing Interventions done, specify**
- **1. Which circulation interventions and adjuncts were performed?** Source: Observation

1. None
2. Control of external bleeding
3. Fluid bolus
4. Blood transfusion
5. eFast
6. Pelvic binder applied
7. Reduction of highly displaced fracture
8. Other
9. Not known

- **2. If other circulation Interventions done, specify**
- **1. Which disability intervention was performed?** Source: Observation

1. None
2. Placement of definitive airway if the patient had a GCS of 8 or less
3. Log Rolling
4. Spine board during transportation
5. Other
6. Not known

- **2. If other disability interventions done, specify**
- **1. Which exposure intervention was performed?** Source: Observation

1. None
2. Covered with warmer or blanket
3. Warm fluids administered
4. Other
5. Not known

- **2. If other exposure interventions done, specify**

13.2.7 Emergency department

- **1. Date and time of arrival to the emergency department at the participating hospital** Source: Medical record of interview
- **2. First recorded systolic blood pressure (mmHg)** Source: Medical record
- **3. First recorded diastolic blood pressure (mmHg)** Source: Medical record
- **4. First recorded heart rate (beats per minute)** Source: Medical record
- **5. First recorded respiratory rate (breaths per minute)** Source: Medical record
- **6. First recorded Glasgow Coma Scale** Source: Medical record
- **7. First recorded body temperature (°C)** Source: Medical record
- **8. First recorded oxygen saturation (%)** Source: Medical record
- **9. Emergency department disposition** Source: Medical record

    1. Admitted
    2. Referred or transferred for admission
    3. Dead
    4. Others
    5. Not known

- **10. If other, please specify** Source: Medical record
- **11. Date and time of referral or transfer for admission** Source: Medical record

13.2.8 Hospital

- **1. Date of admission to the participating hospital** Source: Medical record
- **1.1 Time of admission to the participating hospital** Source: Medical record
- **2. Type of admitting ward** Source: Medical record

    1. General surgery
    2. Orthopaedics
    3. Neurosurgery
    4. Intensive care unit
    5. High dependency unit
    6. Medicine
    7. Trauma ward
    8. Not known

- **3. Ward name or number** Source: Medical record
- **4. Admitted to intensive care unit during admission** Source: Medical record

    1. Yes
    2. No
    3. Not known

- **5. Date of first intensive care unit admission** Source: Medical record
- **5.1 Time of first intensive care unit admission** Source: Medical record
- **6. Date of first intensive care unit discharge** Source: Medical record
- **6.1 Time of first intensive care unit discharge** Source: Medical record
- **7. Hospital disposition** Source: Medical record

    1. Alive
    2. Dead
    3. Transferred for admission
    4. Not known

- **8. Was the patient transferred to another hospital for admission?** Source: Medical record

    1. Yes
    2. No
    3. Not known

- **9. Date of discharge or transfer from participating hospital** Source: Medical record
- **9.1 Time of discharge or transfer from participating hospital** Source: Medical record

13.2.9 Surgery

- **1. Date of surgical procedure** A surgical procedure is defined as any procedure performed in the operating room, interventional dropdownlogy suite, or at the bedside, requiring general or regional anesthesia. Source: Medical record
- **1. Time of surgical procedure** A surgical procedure is defined as any procedure performed in the operating room, interventional dropdownlogy suite, or at the bedside, requiring general or regional anesthesia. Source: Medical record
- **2. Preoperative ASA score** Source: Medical record or treating physician

    1. 1. A normal healthy patient

2. 2. A patient with mild systemic disease
3. 3. A patient with severe systemic disease
4. 4. A patient with severe systemic disease that is a constant threat to life
5. 5. A moribund patient who is not expected to survive without the operation
6. 6. A declared brain-dead patient whose organs are being removed for donor purposes
7. 999. Not known

- **3. Description of procedure** Source: Medical record
- **4. Procedure coded according to SNOMED CT** Source: Medical record

13.2.10 Imaging

- **1. Date and time of imaging** Source: Medical record
- **1.1 Time of imaging** Source: Medical record
- **2. Type of imaging** Source: Medical record

1. Ultrasound
2. X-ray
3. Computed Tomography (CT)
4. Magnetic Resonance Imaging (MRI)

13.2.11 Transfusion

- **1. Date of transfusion** Source: Medical record
- **1.1 Time of transfusion** Source: Medical record
- **2. Type of blood product** Source: Medical record

1. Packed red blood cells
2. Platelets
3. Fresh frozen plasma
4. Whole blood
5. Other

- **2.1 Other specify**
- **3. Number of units transfused** Source: Medical record

13.2.12 Injury

- **1. Injury description** Source: Medical record
- **2. ICD 10 code** Coded using ICD 10. Source: Medical record
- **3. Injury source data** Source: Medical record

    1. Medical record
    2. X-ray report
    3. CT-report
    4. Surgical notes

- **4. Injury time**

13.2.13 Individual mortality status

- **1. Is the patient dead?** Source: Medical record or interview

    1. Yes
    2. No

- **2. Date and time of death** Source: Medical record or interview

13.2.14 Quality of life (EQ5D5L)

- **Date of filling this form**
- **First, I would like to ask you about MOBILITY. Would you say that:** Requires opt-in consent, not routinely recorded. Source: Interview

    1. You have no problems in walking about?
    2. You have slight problems in walking about?
    3. You have moderate problems in walking about?
    4. You have severe problems in walking about?
    5. You are unable to walk about?

- **Next, I would like to ask you about SELF-CARE. Would you say that:** Requires opt-in consent, not routinely recorded. Source: Interview

    1. You have no problems washing or dressing yourself?
    2. You have slight problems washing or dressing yourself?
    3. You have moderate problems washing or dressing yourself?
    4. You have severe problems washing or dressing yourself?
    5. You are unable to wash or dress yourself?

- **Next, I would like to ask you about USUAL ACTIVITIES, for example, work, study, housework, family or leisure activities. Would you say that:** Requires opt-in consent, not routinely recorded. Source: Interview

    1. You have no problems doing your usual activities?
    2. You have slight problems doing your usual activities?
    3. You have moderate problems doing your usual activities?
    4. You have severe problems doing your usual activities?
    5. You are unable to do your usual activities?

- **Next, I would like to ask you about PAIN OR DISCOMFORT. Would you say that:** Requires opt-in consent, not routinely recorded. Source: Interview

    1. You have no pain or discomfort?
    2. You have slight pain or discomfort?
    3. You have moderate pain or discomfort?
    4. You have severe pain or discomfort?
    5. You have extreme pain or discomfort?

- **Finally, I would like to ask you about ANXIETY OR DEPRESSION. Would you say that:** Requires opt-in consent, not routinely recorded. Source: Interview

    1. You are not anxious or depressed?
    2. You are slightly anxious or depressed?
    3. You are moderately anxious or depressed?
    4. You are severely anxious or depressed?
    5. You are extremely anxious or depressed?

- **I would now like you to tell me the point on this line where you would put your health TODAY.(Note to interviewer: mark the line at the point indicating the respondent's health today.)** Requires opt-in consent, not routinely recorded. Source: Interview

13.2.15 Disability (WHODAS 2.0)

- **Date of form filling**
- **1. Who are you interviewing?** Requires opt-in consent, not routinely recorded. Source: Interview

    1. Patient participant
    2. Patient representative

- **2. What is the relationship between the representative and the participant?** Requires opt-in consent, not routinely recorded. Source: Interview

1. Husband or wife
2. Parent
3. Son or daughter
4. Brother or sister
5. Other relative
6. Friend
7. Professional carer
8. Other (specify)

- **3. If other, please specify**
- **1. Standing for long periods such as 30 minutes?** Requires opt-in consent, not routinely recorded. Source: Interview

1. None
2. Mild
3. Moderate
4. Severe
5. Extreme or cannot do
6. None
7. Mild
8. Moderate
9. Severe
10. Extreme or cannot do

- **2. Taking care of your household responsibilities?** Requires opt-in consent, not routinely recorded. Source: Interview

1. None
2. Mild
3. Moderate
4. Severe
5. Extreme or cannot do

- **3. Learning a new task, for example, learning how to get to a new place?** Requires opt-in consent, not routinely recorded. Source: Interview

1. None
2. Mild
3. Moderate
4. Severe
5. Extreme or cannot do
6. None
7. Mild
8. Moderate

9. Severe
10. Extreme or cannot do

- **4. How much of a problem did you have joining in community activities (for example, festivities, religious or other activities) in the same way as anyone else can?** Requires opt-in consent, not routinely recorded. Source: Interview

    1. None
    2. Mild
    3. Moderate
    4. Severe
    5. Extreme or cannot do

- **5. How much have you been emotionally affected by your health problems?** Requires opt-in consent, not routinely recorded. Source: Interview

    1. None
    2. Mild
    3. Moderate
    4. Severe
    5. Extreme or cannot do

- **1. Concentrating on doing something for ten minutes?** Requires opt-in consent, not routinely recorded. Source: Interview

    1. None
    2. Mild
    3. Moderate
    4. Severe
    5. Extreme or cannot do
    6. None
    7. Mild
    8. Moderate
    9. Severe
    10. Extreme or cannot do

- **2. Walking a long distance such as a kilometre [or equivalent]?** Requires opt-in consent, not routinely recorded. Source: Interview

    1. None
    2. Mild
    3. Moderate
    4. Severe
    5. Extreme or cannot do
    6. None

7. Mild
8. Moderate
9. Severe
10. Extreme or cannot do

- **3. Washing your whole body?** Requires opt-in consent, not routinely recorded. Source: Interview

1. None
2. Mild
3. Moderate
4. Severe
5. Extreme or cannot do

- **4. Getting dressed?** Requires opt-in consent, not routinely recorded. Source: Interview

1. None
2. Mild
3. Moderate
4. Severe
5. Extreme or cannot do
6. None
7. Mild
8. Moderate
9. Severe
10. Extreme or cannot do

- **5. Dealing with people you do not know?** Requires opt-in consent, not routinely recorded. Source: Interview

1. None
2. Mild
3. Moderate
4. Severe
5. Extreme or cannot do

- **6. Maintaining a friendship?** Requires opt-in consent, not routinely recorded. Source: Interview

1. None
2. Mild
3. Moderate
4. Severe
5. Extreme or cannot do
6. None

7. Mild
8. Moderate
9. Severe
10. Extreme or cannot do

- **7. Your day-to-day work/school?** Requires opt-in consent, not routinely recorded. Source: Interview

  1. None
  2. Mild
  3. Moderate
  4. Severe
  5. Extreme or cannot do

- **2. Taking care of his or her household responsibilities?** Requires opt-in consent, not routinely recorded. Source: Interview

  1. None
  2. Mild
  3. Moderate
  4. Severe
  5. Extreme or cannot do

- **4. How much of a problem did he or she have joining in community activities (for example, festivities, religious or other activities) in the same way as anyone else can?** Requires opt-in consent, not routinely recorded. Source: Interview

  1. None
  2. Mild
  3. Moderate
  4. Severe
  5. Extreme or cannot do

- **5. How much has your relative been emotionally affected by his or her health condition?** Requires opt-in consent, not routinely recorded. Source: Interview

  1. None
  2. Mild
  3. Moderate
  4. Severe
  5. Extreme or cannot do

- **3. Washing his or her whole body?** Requires opt-in consent, not routinely recorded. Source: Interview

1. None
2. Mild
3. Moderate
4. Severe
5. Extreme or cannot do

- **5. Dealing with people he or she does not know?** Requires opt-in consent, not routinely recorded. Source: Interview

  1. None
  2. Mild
  3. Moderate
  4. Severe
  5. Extreme or cannot do

- **7. His or her day-to-day work/school?** Requires opt-in consent, not routinely recorded. Source: Interview

  1. None
  2. Mild
  3. Moderate
  4. Severe
  5. Extreme or cannot do

- **1. Overall, in the past 30 days, how many days were these difficulties present?** Requires opt-in consent, not routinely recorded. Source: Interview
- **2. In the past 30 days, for how many days were you totally unable to carry out your usual activities or work because of any health condition?** Requires opt-in consent, not routinely recorded. Source: Interview
- **3. In the past 30 days, not counting the days that you were totally unable, for how many days did you cut back or reduce your usual activities or work because of any health condition?** Requires opt-in consent, not routinely recorded. Source: Interview

13.2.16 Return to work

- **Date of form filling**
- **1. Did participant returned to work?**

  1. Yes
  2. No

- **2. Date and time of return to work** Requires opt-in consent, not routinely recorded. Source: Interview
- **3. Work status** Requires opt-in consent, not routinely recorded. Source: Interview

    1. Paid work
    2. Self-employed, such as own your business or farming
    3. Non-paid work, such as volunteer or charity
    4. Student
    5. Keeping house/homemaker
    6. Not known

13.2.17 Safety events

- **1. Date reported to trial management team of safety event**
- **2. Type of safety event** Source: Medical record or treating physician

    1. Prolonged mechanical ventilation (> 7 days)
    2. Initiation of renal replacement therapy
    3. Prolonged (> 2 days) use of vasopressors such as norepinephrine or vasopressin
    4. Renewed (restart after at least 2 days without) use of vasopressors such as norepinephrine or vasopressin
    5. Other

- **3. Elaborate on other safety event** Source: Medical record or treating physician
- **4. Investigator assessment of safety event** Source: Investigator

13.2.18 End of study

- **1. What is the reason for the end of study?**

    1. Completed follow up
    2. Lost to follow up
    3. Death
    4. Discharge and no consent for follow up
    5. Opt-out from routinely recorded (in-hospital) data collection and no consent for follow-up
    6. Opt-out from routinely recorded (in-hospital) data collection and withdrawn consent for follow-up

- **2. Date and time of end of study**

14 Trial organisation

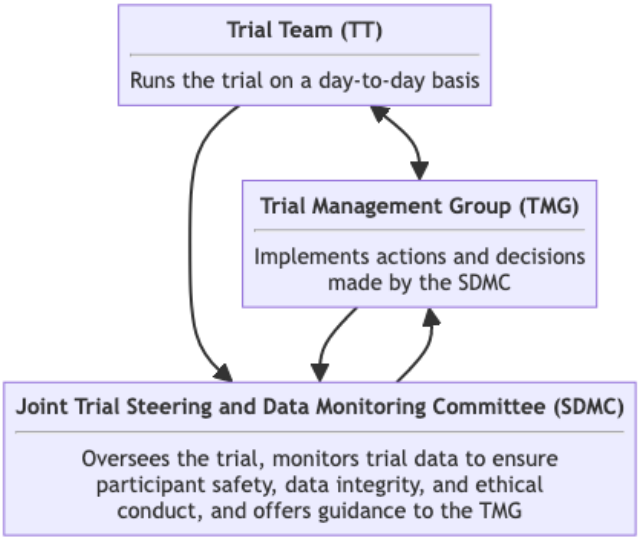

Figure 4: Trial organisation overview.

Trial management and oversight is governed by three trial committees and groups: the Trial Team (TT), the Trial Management Group (TMG), the joint Trial Steering and Data Monitoring Committee (SDMC). These groups and their relationships are briefly described in Figure 4. Details about each committee and group are available in their respective charter.

14.1 Trial team

Responsibility

To run the trial on a day-to-day basis, maintain trial databases, randomise clusters, ensuring complete and correct data, preparing reports for meetings (including those of the TMG and SDMC) and dealing with research governance and, if appropriate, regulatory matters.

Composition

Includes the project manager, clinical research associates, principal investigator and co-investigators as needed.

Relationships

Reports to the TMG and SDMC. Operationalises decisions made by the TMG.

Meeting frequencies

As often as needed, often weekly or bi-weekly.

14.2 Trial Management Group (TMG)

Responsibility

To manage the trial, including its clinical and practical aspects.

Composition

Includes members with broad expertise appropriate to the trial. The TMG will be chaired by the Principal Investigator.

Relationships

Receives reports from TT. Provides input to the SDMC. Implements decisions made by the SDMC.

Meeting frequencies

Monthly to every six months.

14.3 Joint Trial Steering and Data Monitoring Committee (SDMC)

Responsibility

The SDMC's responsibility is to oversee the trial, review results of interim analyses and safety events reported by the TMG, and review trial data for each batch, assessing data quality, completeness, cluster performance in recruitment and loss to follow-up rates, and external factors affecting trial validity, safety, or ethics. This committee also offer guidance to the TMG.

Composition

A majority of independent members, including a chair and three additional external experts specializing in the clinical area, biostatistics, and a community or patient representative, as well as and a minority of members with a direct interest in the trial, including the principal investigator. The chair should be independent of the trial, and the coordinating institutions Karolinska Institutet and The George Institute for Global Health.

Relationships

Receives reports from the trial team and TMG.

Meeting frequencies

After the completion of each batch, but may be more frequent if needed.

15 Funding

- Swedish Research Council (reg. no. 2023-03128)
- Laerdal Foundation (reg. no. 2023-0297)

16 Special considerations

16.1 Funding

This trial is not yet fully funded. The Trial Management Group has decided to proceed with the trial with the expectation that additional funding will be secured. The Trial Steering Committee will be informed of the funding status at each meeting. If funding is not secured, the trial will be stopped. This will likely result in an underpowered trial. The justification for this decision is that the intervention is considered standard of care in many countries and the data collection is considered minimal risk. There is therefore a very small risk of harm to patient participants, but a potential direct benefit to those patient participants who receive the intervention. The benefit-risk ratio is therefore considered to be favourable, even in the case of an underpowered trial.

16.2 Potential amendments

There are ongoing discussions about re-framing the trial as a hybrid effectiveness-implementation trial and include a cost-effectiveness analysis. This would involve adding additional data collection to assess the implementation and costs of the intervention. This would involve additional funding and amended ethical approvals.

17 Notification of trial completion, reporting, and publication

The trial will be reported to the Funders within a year of completion. The results of the trial will also be prepared as manuscripts for publication. Authorship on trial manuscripts will be based on the International Committee of Medical Journal Editors (ICMJE) criteria[43]:

- Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND
- Drafting the work or reviewing it critically for important intellectual content; AND
- Final approval of the version to be published; AND

- Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

In addition to being accountable for the parts of the work done, an author should be able to identify which co-authors are responsible for specific other parts of the work. In addition, authors should have confidence in the integrity of the contributions of their co-authors.

The most recent version of the ICMJE criteria will be adhered to. We will also use the ICMJE criteria for non-author contributorship.

Before work on a trial manuscript is initiated, a writing group will be formed and first and last authors will be designated. This writing group will be formed by discussion in the Trial Management Group.

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43. ICMJE | Recommendations | Defining the Role of Authors and Contributors.

19 Appendices

19.1 Initial hospital screening instrument

Screening call

This form is for screening potentially eligible clusters for the ATLS vs standard care trial. Please fill it in while talking to the hospital representative. Thank you so much for helping with this task!

Please complete the questions below.

Synopsis Title Effects of Advanced Trauma Life Support® Training Compared to Standard Care on Adult Trauma Patient Outcomes: A Cluster Randomised Trial

Rationale Trauma is a massive global health issue. Many training programmes have been developed to help physicians in the initial management of trauma patients. Advanced Trauma Life Support® (ATLS®) is the most popular of these programmes and have been used to train over one million physicians worldwide. Despite its widespread use, there are no controlled trials showing that ATLS® improves patient outcomes. Multiple systematic reviews emphasise the need for such trials.

Aim To compare the effects of ATLS® training with standard care on outcomes in adult trauma patients.

Primary Outcome In-hospital mortality within 30 days of arrival at the emergency department.

Trial Design Batched stepped-wedge cluster randomised trial in India.

Trial Population Adult trauma patients presenting to the emergency department of a participating hospital.

Sample Size 30 clusters and 4320 patients.

Eligibility Criteria

Cluster will be hospitals with a baseline admission rate of at least 400 patients with trauma per year or 35 patients with trauma per month for at least the last six months, that provide emergency surgical and orthopaedic services around the clock, and where no more than 25% of initial trauma care providers trained in a formalised trauma life support training programme.

Patients will be at least 15 years old, who present to the emergency department of participating hospitals with a history of trauma occuring less than 48 hours before arrival, and who are admitted or die between and admission, or who are transferred from the emergency department of a participating hospital to another hospital for admission.

Intervention The intervention will be ATLS® training, a proprietary 2.5 day course teaching a standardised approach to trauma patient care using the concepts of a primary and secondary survey. Physicians will be trained in an accredited ATLS® training facility in India.

Ethical Considerations In-hospital data collection will be conducted under a waiver of informed consent. Patients will be informed about the trial and their right to opt out of data collection. Patients will be informed that they can withdraw their data from the trial at any time.

Trial Period 2024-10-01 to 2029-10-01

Hospital details

Hospital name and address

Eligibility assessment

Does the hospital admit trauma patients?	◯ Yes ◯ No
Is the hospital representative interested in potentially participating?	◯ Yes ◯ No (Comment: _____)
If the hospital representative is not interested in participating then you can go ahead and submit the form.	
How many trauma patients aged 15 years or older, excluding patients with isolated limb injuries, are admitted each month?	◯ < 30 ◯ 30-60 ◯ > 60 ◯ Not sure (Comment: _____)
Does the hospital provide emergency surgery and orthopaedic services around the clock?	◯ Yes ◯ No (Comment: _____)
Out of the physicians involved in the initial resuscitation of trauma patients, are less than 25% trained in a formalised trauma life support training programme like ATLS or Primary Trauma Care?	◯ Yes ◯ No (Comment (like name of other training programme): _____)
Unfortunately, the hospital does not fulfil the eligibility criteria and you may go ahead and submit the form.	

The hospital fulfills the cluster eligibility criteria. Please enter the hospital representative's contact details:

Name E-mail Phone number

_____ _____ _____

Before you can proceed to fill in descriptive information about the potential cluster, please confirm that the contact details are complete:

_____

Cluster descriptive information

Out of the patients with trauma who present to the emergency department, what percentage are referrals or transfers from other hospitals?	◯ < 20% ◯ 20-50% ◯ 51-80% ◯ > 80% ◯ Not sure (Comment: _____)
Out of the patients with trauma who are admitted, what percentage are transferred to other hospitals?	◯ < 10% ◯ 10-20% ◯ 21-30% ◯ >30% ◯ Not sure (Comment: _____)

Who performs the initial resuscitation of trauma patients as they arrive to the hospital?	☐ Casualty medical officers ☐ Emergency medicine residents ☐ Surgical residents ☐ Not sure (Comment: _____)
How many CMOs work in the emergency department? This question is here to help us estimate the number of people we will need to train.	◯ < 10 ◯ 10-20 ◯ 21-30 ◯ > 30 ◯ Not sure (Comment: _____)
How many emergency medicine/general surgery residents are admitted each year? This question is here to help us estimate the number of people we will need to train.	◯ < 10 ◯ 10-20 ◯ 21-30 ◯ > 30 ◯ Not sure (Comment: _____)
What specialities are available around the clock to care for trauma patients?	☐ General surgery ☐ Orthopaedics ☐ Neurosurgery ☐ Vascular surgery ☐ Interventional radiology ☐ Emergency medicine ☐ Not sure (Comment: _____)
What facilities are available around the clock?	☐ X-ray ☐ Ultrasound/FAST ☐ CT ☐ MRI ☐ Blood bank ☐ Not sure (Comment: _____)
How many beds does the hospital have?	◯ < 250 ◯ 250-500 ◯ 501-750 ◯ 751-1000 ◯ >1000 ◯ Not sure (Comment: _____)
How many ICU beds does the hospital have?	◯ No ICU beds ◯ 1-10 ◯ 11-20 ◯ 21-30 ◯ > 30 ◯ Not sure (Comment: _____)
How many dedicated trauma beds does the hospital have?	◯ No dedicated trauma beds ◯ 1-10 ◯ 11-20 ◯ 21-30 ◯ > 30 ◯ Not sure (Comment: _____)

Please submit the form once you have completed all questions above.

19.2 In-depth hospital screening interview instrument

Hospital screening interview for the ATLS vs standard care trial

This is the screening interview form for the Advanced Trauma Life Support® vs Standard Care trial planned by Karolinska Institutet along with The George Institute. You have expressed preliminary interest inparticipating in this trial. We are undertaking this hospital screening interview inorder to assess whether the study could be conducted at your hospital. We appreciate your efforts to answer as many of these questions as possible and we will follow up on your responses and any questions you may have in a separate call. Thank you!

Synopsis Effects of Advanced Trauma Life Support® Training Compared to Standard Care on Adult Trauma Patient Outcomes: A Cluster Randomised Trial Rationale Trauma is a massive global health issue. Many training programmes have been developed to help physicians in the initial management of trauma patients. Among these programmes, Advanced Trauma Life Support® (ATLS®) is the most popular, having trained over one million physicians worldwide. Despite its widespread use, there are no controlled trials showing that ATLS® improves patient outcomes. Multiple systematic reviews emphasise the need for such trials.

Aim To compare the effects of ATLS® training with standard care on outcomes in adult trauma patients.

Primary Outcome All-cause mortality within 30 days of arrival at the emergency department.

Trial Design Batched stepped-wedge cluster randomised trial in India.

Trial Population Adult trauma patients presenting to the emergency department of a participating hospital.

Sample Size 30 clusters and 4320 patients.

Eligibility Criteria

Hospitals are secondary or tertiary hospitals in India that admit or refer/transfer for admission at least 400 patients with trauma per year.

Clusters are one or more units of physicians providing initial trauma care in the emergency department of tertiary hospitals in India.

Patients participants are adult trauma patients who presents to the emergency department of participating hospitals and are admitted or transferred for admission.

Intervention The intervention will be ATLS® training, a proprietary 2.5 day course teaching a standardised approach to trauma patient care using the concepts of a primary and secondary survey. Physicians will be trained in an accredited ATLS® training facility in India.

Ethical Considerations We will use an opt-out consent approach, in which consent is presumed unless actively declined. Note that consent here refers to consent to data collection, as it will not be possible for patients to opt out from being subjected to the intervention. This approach is justified because the trial can be considered to involve only minimal risk and the data

collection is non-invasive and mostly involve extracting routinely collected data from medical records. Patient participants will be informed about the study and their right to opt out once they are admitted or telephonically if they are transferred. Patients will be informed that they can withdraw their data from the trial at any time before final analysis of the data.

Trial Period October 1, 2024, to September 30, 2029

Hospital details

[hospital_address]

Contact person details

Name [contact_name]
E-mail [contact_email]
Phone number [contact_phone_number]

Will you [contact_name] also be the site investigator?	◯ Yes ◯ No

Investigator details

Please enter the name and contact details of the site investigator

Name _____
E-mail _____
Phone number _____

Please enter these additional investigator details

Designation _____
Specialization _____
State Medical Council registration number _____

Is the investigator trained in International Council for Harmonisation, Guideline for Good Clinical Practice (ICH GCP)?	◯ Yes ◯ No
Will there be a co-investigator at your site?	◯ Yes ◯ No
Will you [contact_name] be the co-investigator?	◯ Yes ◯ No

Please enter the name and contact details of the site investigator

Name _____
E-mail _____
Phone number _____

Please enter these additional co-investigator details Designation _____ Specialization _____ State Medical Council registration number _____	
Is the co-investigator trained in International Council for Harmonisation, Guideline for Good Clinical Practice (ICH GCP)?	◯ Yes ◯ No

Ethical review details

Does your hospital have an ethics committee registered with CDSCO?	◯ Yes ◯ No
Please enter the ethics committee registration number	_____
In the next three months when is your IEC meeting up?	_____
What is the expected timeline for ethics review at your site?	_____
In which languages do you think the consent form should be translated, considering the languages spoken by the potential participants treated at your hospital?	_____

Departmental logistics

Does your hospital require any additional departmental review besides the ethics? Can you please elaborate on that review?	_____
Are there any potential logistical issues which may interfere with set up or running ofthis project at your site?	_____ (E.g. contract review, adequate space, lack of resources etc.)
What is the expected timeline for contract review, negotiations and execution (in days)?	_____
What is the maximum expected timeline?	_____

Initial trauma care	
How do patients typically arrive to your hospital?	
Who are involved in the management of trauma patients in the emergency department?	
What happens when additional expertise is needed?	
What is the role of the casualty medical officers?	
Are physicians organised in units?	
How big are those units?	
How are those units composed in terms of residents and faculty?	
How often do the units rotate?	
How many units are there working in the emergency department?	
How many trauma patients aged 15 years or older are admitted per day, excluding patients with isolated limb injuries and those who are admitted directly to the ward?	

Intervention and patient inclusion	
How many patients do you think you could include in to the proposed trial per month? (We need to include at least 12 patients per month)	
What is the basis of your patient enrollment estimate?	(For example database review, emergency department record, review of patient records, other)
Do you see any problems with including 12 patients per month at your site? Can you please elaborate on those problems?	

All hospitals in this trial will receive the intervention. The intervention is that we will train approximately 10 physicians providing initial trauma care in ATLS in your hospital. Who do you think we should train to maximise the effect?	_____ (Surgical residents? Emergency medicine residents? Casualty medical officers? Someone else??)
The time point when the training will be implemented will be randomised, but there will be a minimum of three months between the start of the data collection and the training. The training will happen during a one month long "transition period". How long notice do you need to plan the participation of the physicians from your hospital?	_____
Are you aware of any plans to train providers in any formalised trauma life support training programme during the next few years?	_____
Are you aware of any plans to implement other interventions or changes that may radically change how you treat trauma patients at your site?	_____ (For example building a trauma centre, building a new emergency department, shifting the CT)
If we would like to visit your hospital to observe trauma care delivery in the emergency department and talk to providers, how can that be arranged?	_____

General

How are the patient medical records organised at your site?	☐ Hard-copy ☐ Electronic ☐ Not sure
Do you currently have any competing studies or are you committed to new competing studies?	_____
Do you have access to a computer with high-speed internet access?	◯ Yes ◯ No
Do you currently have the necessary study team including research coordinator and co-investigators to conduct this study? Can you please elaborate on the composition and experience of that team?	_____
What are your expectations of this trial?	_____
Do you have any questions or comments regarding this trial?	_____
Are you interested in participating in this trial?	◯ Yes ◯ No

If you have any questions, feel free to contact Martin Gerdin Wärnberg (martin.gerdin@ki.se), Monty Khajanchi (monta32@gmail.com) or Samriddhi Ranjan (sranjan@georgeinstitute.org.in)

19.3 Case Record Form

Screening V1.0.01.10.24

Screening ID	_____
1. Date of screening	_____
2. Date of data entry	_____

Inclusion criteria	
1. Is the patient at least 15 years old?	◯ Yes ◯ No (Source: Medical record or interview)
2. Did the patient present with a history of trauma defined as having any of the reasons listed in the International Classification of Diseases chapter XX as the reason for presenting? Please see https://icd.who.int/browse10/2019/en#/XX for a complete list of ICD-10 codes	◯ Yes ◯ No (Source: Medical record or interview)
3. Did the trauma occur less than 48 hours before arrival to the hospital?	◯ Yes ◯ No (Source: Medical record or interview)
4. Was the patient admitted?	◯ Yes ◯ No (Source: Medical record)
5. Did the patient die after arrival but before admission?	◯ Yes ◯ No (Source: Medical record)
6. Was the patient transferred to another hospital for admission?	◯ Yes ◯ No (Source: Medical record)

Exclusion criteria	
1. Did the patient present with isolated limb injury?	◯ Yes ◯ No (Source: Medical record)
2. Was the patient directly admitted to a ward without being seen by a physician in the emergency department?	◯ Yes ◯ No (Source: Medical record)

Eligibility

The patient is not eligible for inclusion.

Consent V1.0.01.10.24

Study Consent

In this trial, consent refers to consent for data collection. It is not possible for patients to opt out from being subjected to the intervention, as the intervention is delivered at the cluster level. Patient participants will be included in this trial under the following modes of consent:
• Opt-out consent for collection of routinely recorded data
• Opt-in consent and assent for non-routinely recorded data, including but not restricted to Quality of Life (EQ5D5L), Disability (WHODAS 2.0) and Return to Work.
• Waiver of informed consent for patients who are unconscious or otherwise unable to provide consent and do not have a legally acceptable representative.
When possible, all patient participants must be approached and provided with information about the study, the option to opt out, and consent for collection of non-routinely recorded data.

Section I: Consent Wavier

Please note that the consent for the collection of the routinely recorded data (in-hospital) will be presumed unless actively declined by the participant/ legally acceptable representative (LAR), using the opt-out form. Information for all forms except for baseline characteristics (marital and work status, education and income), follow-up (Quality of Life (EQ5D5L), Disability (WHODAS 2.0) and Return to Work) will be presumed, unless opted-out.

1. Is this patient included under the waiver of informed consent because the patient is unconscious or otherwise unable to provide consent and do not have a legally acceptable representative?	◯ Yes ◯ No

Section II: Opt in consent for follow up data collection

1. Did the participant/ or legally acceptable representative (LAR) provided consent for collection of non-routinely recorded data	◯ Yes ◯ No
2. Who gave consent for collection of non-routinely recorded data?	◯ Patient participant ◯ Legally acceptable representative
3. Relation of LAR with the Participant	_____
4. Why was Legally acceptable representative (LAR) approached for consent for collection of non-routinely recorded data?	☐ The participant is incapacitated because of the trauma ☐ The participant is younger than 18 years
5. Date when participant or legally acceptable representative (LAR) gave consent for collection of non-routinely recorded data?	_____

6. How did the participant or legally acceptable representative (LAR) consent for collection of non-routinely recorded data?	◯ In writing ◯ Verbally
7. Date when the participant was reconsented?	_____

Section III: Assent form

1. Did the minor give assent for collection of non-routinely recorded data?	◯ Yes ◯ No
2. Date when the minor gave assent for collection of non-routinely recorded data.	_____
3. In case the minor refused to participate, date when minor refused	_____

Section IV: Opt out form

1. Is the participant or LAR wants to opt out from study?	◯ Yes ◯ No
2. Who opted-out of the routinely recorded data (in-hospital)?	◯ Patient participant ◯ Legally acceptable representative (LAR)
3. Date when participant or legally acceptable representative (LAR) opted-out.	_____
4. Did the participant or legally acceptable representative (LAR) suggested to delete all the previously recorded data?	◯ Yes ◯ No

Consent_Withdrawn V1.0.01.10.24

Consent withdrawal	
1. Does the participant or legally acceptable representative (LAR) want to withdraw the consent?	◯ Yes ◯ No
2. Date of consent withdrawal for follow-up data collection.	_____
3. Procedure(s) for which consent has been withdrawn	◯ Data collection prior to withdrawal ◯ All data collection after withdrawal ◯ Both

Baseline V1.0.01.10.24

1. Age in years	_____ (Source: Medical record of interview)
2. Sex	◯ Female ◯ Male ◯ Other ◯ Not known (Source: Medical record of interview)
3. Current marital status	◯ Never married ◯ Currently married ◯ Separated ◯ Divorced ◯ Widowed ◯ Cohabiting ◯ Not known (Requires opt-in consent, not routinely recorded. Source: Interview)
4. Education level	◯ Not attended school ◯ Primary school ◯ Secondary school ◯ Higher secondary school ◯ Graduate ◯ Post graduate and above ◯ Other ◯ Not known (Requires opt-in consent, not routinely recorded. Source: Interview)
5. If other, please specify	_____ (Requires opt-in consent, not routinely recorded. Source: Interview)
6. Main work status	◯ Paid work, such as daily wage earner, teacher, factory worker and government employee ◯ Self-employed, such as own your business or farming ◯ Non-paid work, such as volunteer or charity ◯ Student ◯ Keeping house/homemaker ◯ Retired ◯ Unemployed (health reasons) ◯ Unemployed (other reasons) ◯ Other ◯ No income ◯ Not known (Requires opt-in consent, not routinely recorded. Source: Interview)
7. If other, please specify	_____ (Requires opt-in consent, not routinely recorded. Source: Interview)

8. Income level in INR per month	◯ Below 10,000 ◯ 10,001-20,000 ◯ 20,001-30,000 ◯ 30,001-50,000 ◯ 50,001-80,000 ◯ 80,001-1,00,000 ◯ Above 1,00,000 ◯ Not known (Requires opt-in consent, not routinely recorded. Source: Interview)
9. Mechanism of injury	_____ (Coded using ICD 10. Source: Medical record)
10. Clinical Frailty Scale	◯ 1. Very fit ◯ 2. Fit ◯ 3. Managing well ◯ 4. Living with very mild frailty ◯ 5. Living with mild frailty ◯ 6. Living with moderate frailty ◯ 7. Living with severe frailty ◯ 8. Living with very severe frailty ◯ 9. Terminally ill ◯ Not known (Source: Medical record or treating physician)
11. Comorbidities (Charlson Comorbidity Index)	☐ Myocardial infarction ☐ Congestive heart failure ☐ Peripheral vascular disease ☐ Cerebrovascular disease ☐ Dementia ☐ Chronic pulmonary disease ☐ Rheumatologic disease ☐ Peptic ulcer disease ☐ Liver disease ☐ Diabetes ☐ Hemiplegia or paraplegia ☐ Renal disease ☐ Malignancy ☐ Leukemia ☐ Lymphoma ☐ AIDS ☐ Not known ☐ None (Source: Medical record, treating physician or interview)
12. Severity of liver disease	◯ Mild ◯ Moderate or severe ◯ Not known (Source: Medical record, treating physician or interview)
13. Severity of diabetes	◯ Controlled ◯ Uncontrolled ◯ Not known (Source: Medical record, treating physician or interview)

14. Severity of malignancy	◯ Localized ◯ Metastatic tumor ◯ Not known (Source: Medical record, treating physician or interview)

Prehospital V1.0.01.10.24

1. Date and time of injury	_____ (Source: Medical record of interview)
2. Mode of transport to the participating hospital	◯ Ambulance ◯ Police ◯ Private vehicle ◯ Walking ◯ Others ◯ Not known (Source: Medical record of interview)
3. If other, please specify	_____ (Source: Medical record of interview)
4. Referred or transferred to the participating hospital from another hospital	◯ Yes ◯ No ◯ Not known (Source: Medical record of interview)

ATLS adherence V1.1.22.10.24

ATLS adherence checklist

Airway	
1. Airway patency checked	◯ Yes ◯ No (Source: Observation)
Breathing	
1. Chest wall palpated	◯ Yes ◯ No (Source: Observation)
2. Breath sounds checked	◯ Yes ◯ No (Source: Observation)
3. Respiratory rate measured	◯ Yes ◯ No (Source: Observation)
4. Saturation (SpO2) measured	◯ Yes ◯ No (Source: Observation)
Circulation	
1. Heart rate measured	◯ Yes ◯ No (Source: Observation)
2. Blood pressure measured	◯ Yes ◯ No (Source: Observation)
3. Abdomen palpated	◯ Yes ◯ No (Source: Observation)
4. Thighs palpated	◯ Yes ◯ No (Source: Observation)
5. IV access obtained	◯ Yes ◯ No (Source: Observation)

Disability	
1. GCS checked	◯ Yes ◯ No (Source: Observation)
2. Pupils checked	◯ Yes ◯ No (Source: Observation)

Exposure	
1. Patients exposed for assessment	◯ Yes ◯ No
2. Temperature measured	◯ Yes ◯ No (Source: Observation)
3. Interventions and adjuncts performed according to ATLS	

Airway interventions	
1. Which airway interventions were performed?	☐ None ☐ Manual airway procedure such as chin lift or jaw thrust ☐ Nasopharyngeal or Oropharyngeal airway inserted ☐ Supraglottic airway device ☐ Tracheal intubation ☐ Surgical airway ☐ Other ☐ Not known (Source: Observation)
2. If other airway Interventions given, specify	_____
3. Were airway interventions performed while minimising c-spine movement?	◯ Yes ◯ No ◯ Not known (Source: Observation)

Breathing interventions	
1. Which breathing interventions were performed?	☐ None ☐ Oxygen applied ☐ Intracostal drain placement ☐ Other ☐ Not done ☐ Not known (Source: Observation)
2. If other breathing Interventions done, specify	_____

Circulation interventions

1. Which circulation interventions and adjuncts were performed?	☐ None ☐ Control of external bleeding ☐ Fluid bolus ☐ Blood transfusion ☐ eFast ☐ Pelvic binder applied ☐ Reduction of highly displaced fracture ☐ Other ☐ Not known (Source: Observation)
2. If other circulation Interventions done, specify	_____

Disability interventions

1. Which disability intervention was performed?	☐ None ☐ Placement of definitive airway if the patient had a GCS of 8 or less ☐ Log Rolling ☐ Spine board during transportation ☐ Other ☐ Not known (Source: Observation)
2. If other disability interventions done, specify	_____

Exposure interventions

1. Which exposure intervention was performed?	☐ None ☐ Covered with warmer or blanket ☐ Warm fluids administered ☐ Other ☐ Not known (Source: Observation)
2. If other exposure interventions done, specify	_____

Emergency Department V1.0.01.10.24

1. Date and time of arrival to the emergency department at the participating hospital	_____ (Source: Medical record of interview)
2. First recorded systolic blood pressure (mmHg)	_____ (Source: Medical record)
3. First recorded diastolic blood pressure (mmHg)	_____ (Source: Medical record)
4. First recorded heart rate (beats per minute)	_____ (Source: Medical record)
5. First recorded respiratory rate (breaths per minute)	_____ (Source: Medical record)
6. First recorded Glasgow Coma Scale	_____ (Source: Medical record)
7. First recorded body temperature (°C)	_____ (Source: Medical record)
8. First recorded oxygen saturation (%)	_____ (Source: Medical record)
9. Emergency department disposition	◯ Admitted ◯ Referred or transferred for admission ◯ Dead ◯ Others ◯ Not known (Source: Medical record)
10. If other, please specify	_____ (Source: Medical record)
11. Date and time of referral or transfer for admission	_____ (Source: Medical record)

Hospital V1.0.01.10.24

1. Date of admission to the participating hospital	_____ (Source: Medical record)
1.1 Time of admission to the participating hospital	_____ (Source: Medical record)
2. Type of admitting ward	◯ General surgery ◯ Orthopaedics ◯ Neurosurgery ◯ Intensive care unit ◯ High dependency unit ◯ Medicine ◯ Trauma ward ◯ Not known (Source: Medical record)
3. Ward name or number	_____ (Source: Medical record)
4. Admitted to intensive care unit during admission	◯ Yes ◯ No ◯ Not known (Source: Medical record)
5. Date of first intensive care unit admission	_____ (Source: Medical record)
5.1 Time of first intensive care unit admission	_____ (Source: Medical record)
6. Date of first intensive care unit discharge	_____ (Source: Medical record)
6.1 Time of first intensive care unit discharge	_____ (Source: Medical record)
7. Hospital disposition	◯ Alive ◯ Dead ◯ Transferred for admission ◯ Not known (Source: Medical record)
8. Was the patient transferred to another hospital for admission?	◯ Yes ◯ No ◯ Not known (Source: Medical record)

9. Date of discharge or transfer from participating hospital	_____ (Source: Medical record)
9.1 Time of discharge or transfer from participating hospital	_____ (Source: Medical record)

Surgery V1.0.01.10.24

1. Date of surgical procedure	_____ (A surgical procedure is defined as any procedure performed in the operating room, interventional dropdownlogy suite, or at the bedside, requiring general or regional anesthesia. Source: Medical record)
1. Time of surgical procedure	_____ (A surgical procedure is defined as any procedure performed in the operating room, interventional dropdownlogy suite, or at the bedside, requiring general or regional anesthesia. Source: Medical record)
2. Preoperative ASA score	◯ 1. A normal healthy patient ◯ 2. A patient with mild systemic disease ◯ 3. A patient with severe systemic disease ◯ 4. A patient with severe systemic disease that is a constant threat to life ◯ 5. A moribund patient who is not expected to survive without the operation ◯ 6. A declared brain-dead patient whose organs are being removed for donor purposes ◯ 999. Not known (Source: Medical record or treating physician)
3. Description of procedure	_____ (Source: Medical record)
4. Procedure coded according to SNOMED CT	_____ (Source: Medical record)

Imaging V1.0.01.10.24

1. Date and time of imaging	_____ (Source: Medical record)
1.1 Time of imaging	_____ (Source: Medical record)
2. Type of imaging	◯ Ultrasound ◯ X-ray ◯ Computed Tomography (CT) ◯ Magnetic Resonance Imaging (MRI) (Source: Medical record)

Transfusion V1.0.01.10.24

1. Date of transfusion	_____ (Source: Medical record)
1.1 Time of transfusion	_____ (Source: Medical record)
2. Type of blood product	◯ Packed red blood cells ◯ Platelets ◯ Fresh frozen plasma ◯ Whole blood ◯ Other (Source: Medical record)
2.1 Other specify	_____
3. Number of units transfused	_____ (Source: Medical record)

Injury V1.0.01.10.24

1. Injury description	_____ (Source: Medical record)
2. ICD 10 code	_____ (Coded using ICD 10. Source: Medical record)
3. Injury source data	◯ Medical record ◯ X-ray report ◯ CT-report ◯ Surgical notes (Source: Medical record)
4. Injury time	_____

Individual Mortality Status V1.0.01.10.24

1. Is the patient dead?	◯ Yes ◯ No (Source: Medical record or interview)
2. Date and time of death	_____ (Source: Medical record or interview)

Health Questionnaire

English version

VERSION FOR INTERVIEWER ADMINISTRATION

Note to interviewer: although allowance should be made for the interviewer's particular style of speaking, the wording of the questionnaire instructions should be followed as closely as possible. In the case of the EQ-5D-5L descriptive system of the questionnaire, the precise wording must be followed.

If the respondent has difficulty choosing a response or asks for clarification, the interviewer should repeat the question word for word and ask the respondent to answer in a way that most closely resembles his or her thoughts about his or her health today.

INTRODUCTION

(Note to interviewer: please read the following to the respondent.)

We are trying to find out what you think about your health. I will explain what to do as I go along, but please interrupt me if you do not understand something or if things are not clear to you. There are no right or wrong answers. We are interested only in your personal view.

First, I am going to read out some questions. Each question has a choice of five answers. Please tell me which answer best describes your health TODAY.

Do not choose more than one answer in each group of questions.

(Note to interviewer: first read all five options for each question. Then ask the respondent to choose which one applies to him/herself. Repeat the question and options if necessary. Mark the appropriate box under each heading. You may need to remind the respondent regularly that the timeframe is TODAY.)

EQ-5D DESCRIPTIVE SYSTEM

Date of filling this form _____

First, I would like to ask you about MOBILITY. Would you say that:
(Requires opt-in consent, not routinely recorded. Source: Interview)

◯ You have no problems in walking about?
◯ You have slight problems in walking about?
◯ You have moderate problems in walking about?
◯ You have severe problems in walking about?
◯ You are unable to walk about?

Next, I would like to ask you about SELF-CARE. Would you say that:
(Requires opt-in consent, not routinely recorded. Source: Interview)

◯ You have no problems washing or dressing yourself?
◯ You have slight problems washing or dressing yourself?
◯ You have moderate problems washing or dressing yourself?
◯ You have severe problems washing or dressing yourself?
◯ You are unable to wash or dress yourself?

Next, I would like to ask you about USUAL ACTIVITIES, for example, work, study, housework, family or leisure activities. Would you say that:
(Requires opt-in consent, not routinely recorded. Source: Interview)

◯ You have no problems doing your usual activities?
◯ You have slight problems doing your usual activities?
◯ You have moderate problems doing your usual activities?
◯ You have severe problems doing your usual activities?
◯ You are unable to do your usual activities?

Next, I would like to ask you about PAIN OR DISCOMFORT. Would you say that:
(Requires opt-in consent, not routinely recorded. Source: Interview)

◯ You have no pain or discomfort?
◯ You have slight pain or discomfort?
◯ You have moderate pain or discomfort?
◯ You have severe pain or discomfort?
◯ You have extreme pain or discomfort?

Finally, I would like to ask you about ANXIETY OR DEPRESSION. Would you say that:
(Requires opt-in consent, not routinely recorded. Source: Interview)

◯ You are not anxious or depressed?
◯ You are slightly anxious or depressed?
◯ You are moderately anxious or depressed?
◯ You are severely anxious or depressed?
◯ You are extremely anxious or depressed?

EQ-5D VAS

Now, I would like to ask you to say how good or bad your health is TODAY.

I would like you to picture in your mind a vertical line that is numbered from 0 to 100.
(Note to interviewer: if interviewing face-to-face, please show the respondent the VAS line.)

100 at the top of the line means the best health you can imagine.
0 at the bottom of the line means the worst health you can imagine.

I would now like you to tell me the point on this line where you would put your health TODAY.
(Note to interviewer: mark the line at the point indicating the respondent's health today.)

0 - The worst health you can imagine

50

100 - The best health you can imagine

(Place a mark on the scale above)

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Disability (WHODAS 2.0)

Date of form filling	_____
1. Who are you interviewing?	◯ Patient participant ◯ Patient representative (Requires opt-in consent, not routinely recorded. Source: Interview)
2. What is the relationship between the representative and the participant?	◯ Husband or wife ◯ Parent ◯ Son or daughter ◯ Brother or sister ◯ Other relative ◯ Friend ◯ Professional carer ◯ Other (specify) (Requires opt-in consent, not routinely recorded. Source: Interview)
3. If other, please specify	_____

Instructions to the interviewer are written in bold - do not read these aloud.

Text for the respondent to hear is written in italic print in blue. Read this text aloud.

Say to respondent:
The interview is about difficulties people have because of health conditions.

By health condition I mean diseases or illnesses, or other health problems that may be short or long lasting; injuries; mental or emotional problems; and problems with alcohol or drugs.

Remember to keep all of your health problems in mind as you answer the questions. When I ask you about difficulties in doing an activity think about...

Increased effort Discomfort or pain Slowness Changes in the way you do the activity When answering, I'd like you to think back over the past 30 days. I would also like you to answer these questions thinking about how much difficulty you have had, on average, over the past 30 days, while doing the activity as you usually do it.

Use this scale when responding: None, mild, moderate, severe, extreme or cannot do.

In the past 30 days, how much difficulty did you have in:

1. Standing for long periods such as 30 minutes?	◯ None ◯ Mild ◯ Moderate ◯ Severe ◯ Extreme or cannot do (Requires opt-in consent, not routinely recorded. Source: Interview)
2. Taking care of your household responsibilities?	◯ None ◯ Mild ◯ Moderate ◯ Severe ◯ Extreme or cannot do (Requires opt-in consent, not routinely recorded. Source: Interview)
3. Learning a new task, for example, learning how to get to a new place?	◯ None ◯ Mild ◯ Moderate ◯ Severe ◯ Extreme or cannot do (Requires opt-in consent, not routinely recorded. Source: Interview)
4. How much of a problem did you have joining in community activities (for example, festivities, religious or other activities) in the same way as anyone else can?	◯ None ◯ Mild ◯ Moderate ◯ Severe ◯ Extreme or cannot do (Requires opt-in consent, not routinely recorded. Source: Interview)
5. How much have you been emotionally affected by your health problems?	◯ None ◯ Mild ◯ Moderate ◯ Severe ◯ Extreme or cannot do (Requires opt-in consent, not routinely recorded. Source: Interview)
In the past 30 days, how much difficulty did you have in:	
1. Concentrating on doing something for ten minutes?	◯ None ◯ Mild ◯ Moderate ◯ Severe ◯ Extreme or cannot do (Requires opt-in consent, not routinely recorded. Source: Interview)
2. Walking a long distance such as a kilometre [or equivalent]?	◯ None ◯ Mild ◯ Moderate ◯ Severe ◯ Extreme or cannot do (Requires opt-in consent, not routinely recorded. Source: Interview)

3. Washing your whole body?	◯ None ◯ Mild ◯ Moderate ◯ Severe ◯ Extreme or cannot do (Requires opt-in consent, not routinely recorded. Source: Interview)
4. Getting dressed?	◯ None ◯ Mild ◯ Moderate ◯ Severe ◯ Extreme or cannot do (Requires opt-in consent, not routinely recorded. Source: Interview)
5. Dealing with people you do not know?	◯ None ◯ Mild ◯ Moderate ◯ Severe ◯ Extreme or cannot do (Requires opt-in consent, not routinely recorded. Source: Interview)
6. Maintaining a friendship?	◯ None ◯ Mild ◯ Moderate ◯ Severe ◯ Extreme or cannot do (Requires opt-in consent, not routinely recorded. Source: Interview)
7. Your day-to-day work/school?	◯ None ◯ Mild ◯ Moderate ◯ Severe ◯ Extreme or cannot do (Requires opt-in consent, not routinely recorded. Source: Interview)

Instructions to the interviewer are written in bold - do not read these aloud.

Text for the respondent to hear is written in italic print in blue. Read this text aloud.

Say to respondent:
The interview is about difficulties people have because of health conditions.

By health condition I mean diseases or illnesses, or other health problems that may be short or long lasting; injuries; mental or emotional problems; and problems with alcohol or drugs.

Remember to keep all of your health problems in mind as you answer the questions. When I ask you about difficulties in doing an activity think about...

Increased effort Discomfort or pain Slowness Changes in the way you do the activity When answering, I'd like you to think back over the past 30 days and, to the best of your knowledge, answer these questions thinking about how much difficulty your friend, relative or carer had while doing the following activities. I will use the term "relative" to mean "friend", "relative"

or "carer". For each question, please give only one response.

In the past 30 days, how much difficulty did your relative have in:

1. Standing for long periods such as 30 minutes?	◯ None ◯ Mild ◯ Moderate ◯ Severe ◯ Extreme or cannot do (Requires opt-in consent, not routinely recorded. Source: Interview)
2. Taking care of his or her household responsibilities?	◯ None ◯ Mild ◯ Moderate ◯ Severe ◯ Extreme or cannot do (Requires opt-in consent, not routinely recorded. Source: Interview)
3. Learning a new task, for example, learning how to get to a new place?	◯ None ◯ Mild ◯ Moderate ◯ Severe ◯ Extreme or cannot do (Requires opt-in consent, not routinely recorded. Source: Interview)
4. How much of a problem did he or she have joining in community activities (for example, festivities, religious or other activities) in the same way as anyone else can?	◯ None ◯ Mild ◯ Moderate ◯ Severe ◯ Extreme or cannot do (Requires opt-in consent, not routinely recorded. Source: Interview)
5. How much has your relative been emotionally affected by his or her health condition?	◯ None ◯ Mild ◯ Moderate ◯ Severe ◯ Extreme or cannot do (Requires opt-in consent, not routinely recorded. Source: Interview)

In the past 30 days, how much difficulty did your relative have in:

1. Concentrating on doing something for ten minutes?	◯ None ◯ Mild ◯ Moderate ◯ Severe ◯ Extreme or cannot do (Requires opt-in consent, not routinely recorded. Source: Interview)
2. Walking a long distance such as a kilometre [or equivalent]?	◯ None ◯ Mild ◯ Moderate ◯ Severe ◯ Extreme or cannot do (Requires opt-in consent, not routinely recorded. Source: Interview)

3. Washing his or her whole body?	◯ None ◯ Mild ◯ Moderate ◯ Severe ◯ Extreme or cannot do (Requires opt-in consent, not routinely recorded. Source: Interview)
4. Getting dressed?	◯ None ◯ Mild ◯ Moderate ◯ Severe ◯ Extreme or cannot do (Requires opt-in consent, not routinely recorded. Source: Interview)
5. Dealing with people he or she does not know?	◯ None ◯ Mild ◯ Moderate ◯ Severe ◯ Extreme or cannot do (Requires opt-in consent, not routinely recorded. Source: Interview)
6. Maintaining a friendship?	◯ None ◯ Mild ◯ Moderate ◯ Severe ◯ Extreme or cannot do (Requires opt-in consent, not routinely recorded. Source: Interview)
7. His or her day-to-day work/school?	◯ None ◯ Mild ◯ Moderate ◯ Severe ◯ Extreme or cannot do (Requires opt-in consent, not routinely recorded. Source: Interview)
Number of days	
1. Overall, in the past 30 days, how many days were these difficulties present?	_____ (Requires opt-in consent, not routinely recorded. Source: Interview)
2. In the past 30 days, for how many days were you totally unable to carry out your usual activities or work because of any health condition?	_____ (Requires opt-in consent, not routinely recorded. Source: Interview)
3. In the past 30 days, not counting the days that you were totally unable, for how many days did you cut back or reduce your usual activities or work because of any health condition?	_____ (Requires opt-in consent, not routinely recorded. Source: Interview)

Return To Work V1.0.01.10.24

Date of form filling	_____
1. Did participant returned to work?	◯ Yes ◯ No
2. Date and time of return to work	_____ (Requires opt-in consent, not routinely recorded. Source: Interview)
3. Work status	◯ Paid work ◯ Self-employed, such as own your business or farming ◯ Non-paid work, such as volunteer or charity ◯ Student ◯ Keeping house/homemaker ◯ Not known (Requires opt-in consent, not routinely recorded. Source: Interview)

Safety Events V1.0.01.10.24

1. Date reported to trial management team of safety event	_____
2. Type of safety event	◯ Prolonged mechanical ventilation (> 7 days) ◯ Initiation of renal replacement therapy ◯ Prolonged (> 2 days) use of vasopressors such as norepinephrine or vasopressin ◯ Renewed (restart after at least 2 days without) use of vasopressors such as norepinephrine or vasopressin ◯ Other (Source: Medical record or treating physician)
3. Elaborate on other safety event	_____ (Source: Medical record or treating physician)
4. Investigator assessment of safety event	_____ (Source: Investigator)

End Of Study V1.0.01.10.24

1. What is the reason for the end of study?	◯ Completed follow up ◯ Lost to follow up ◯ Death ◯ Discharge and no consent for follow up ◯ Opt-out from routinely recorded (in-hospital) data collection and no consent for follow-up ◯ Opt-out from routinely recorded (in-hospital) data collection and withdrawn consent for follow-up
2. Date and time of end of study	_____

End Of Study V10 Dated22mar24

What is the reason for the end of study?	◯ Completed follow up ◯ Lost to follow up ◯ Death ◯ Discharge and no consent for follow up ◯ Opt-out from routinely recorded (in-hospital) data collection and no consent for follow-up ◯ Opt-out from routinely recorded (in-hospital) data collection and withdrawn consent for follow-up
Date and time of end of study	_____

Martin Gerdin Wärnberg, CV

BIRTH DATA

27 January 1988

ADDRESS

Residence

Tulegatan 47, 113 53 Stockholm

Workplaces

Department of Global Public Health, Karolinska Institutet, 171 77 Stockholm

Function Perioperative Medicine and Intensive Care, Karolinska University Hospital, Eugeniavägen 3, Solna, 171 76 Stockholm

PHONE AND EMAIL

+46 708 53 95 98, martin.gerdin@ki.se

CURRENT EDUCATIONAL ACTIVITY

I am the programme director of the Master's Programme in Global Health and I am the course leader of the Degree Project in Global Health course at Karolinska Institutet. Global health is a rapidly developing field that deals with the multifaceted health challenges that transcend national borders and impact both current and future generations.

CURRENT SCIENTIFIC ACTIVITY

My research aims to improve the evidence base for system-level interventions in trauma care. Every year, trauma—such as road traffic injuries—is a leading cause of mortality and morbidity worldwide. I lead large-scale research on the effects of interventions, such as trauma life support training and quality improvement programmes, on patient outcomes.

COURSES AND DEGREES

2024 | Coaching leadership (2 days), KC Group, Stockholm

2024 | Two2Tango – Tandems for Teaching in the glocal classroom (2 weeks), Karolinska Institutet

2023 | Pedagogy for doctoral supervisors (2 weeks), Karolinska Institutet

2018 | Teaching and learning in higher education (5 weeks), Karolinska Institutet

2017 | Introductory doctoral supervision course (1 week), Karolinska Institutet

2014 | Degree Of Master Of Science In Medicine, Karolinska Institutet

DOCTORAL DEGREE

2015 | Degree Of Doctor Of Philosophy Department of Global Public Health, Karolinska Institutet, Stockholm, Sweden. Thesis title: The risk of dying: predicting trauma mortality in urban Indian hospi-

tals. URL: http://hdl.handle.net/10616/44832. Main supervisor: Johan von Schreeb, co-supervisor: Li Felländer-Tsai, Göran Tomson, Max Petzold.

POSTDOC APPOINTMENTS

2018–2023 | Postdoctoral Researcher, Department of Global Public Health, Karolinska Institutet, Stockholm, Sweden.

DOCENT-LEVEL COMPETENCE

2020 | Karolinska Institutet, Stockholm, Sweden

CURRENT POSITION

2023– | Principal Researcher, Department of Global Public Health, Karolinska Institutet, Stockholm, Sweden

2020– | Resident in Anaesthesia and Intensive care, Perioperative Medicine and Intensive Care, Karolinska University Hospital

PRIOR POSITIONS

2018–2023 | Postdoctoral Researcher, Department of Global Public Health, Karolinska Institutet

2015–2108 | Research Intern, Department of Global Public Health, Karolinska Institutet and Karolinska University Hospital

2012–2016 | Doctoral Student, Department of Global Public Health, Karolinska Institutet

2011–2012 | Research Assistant, Department of Global Public Health, Karolinska Institutet

TIME DEDUCTED FROM ACTIVE RESEARCH AND EDUCATION TIME

2020– | Ongoing residency in anaesthesia and intensive care (85%, 30 months)

2019–2020 | Parental leave (85%, 9 months)

2018–2019 | Parental leave (85%, 6 months)

2015–2018 | Clinical rotations in primary care, psychiatry, surgery, anesthesia, orthopedics and internal medicine during medical internship (AT) (100%, 18 months)

SELECTED ACADEMIC DISTINCTIONS AND OTHER MERITS

2024– | Programme Director, Master's Programme in Global Health, Karolinska Institutet (25%)

2023– | Team Leader, No Accidents: Improving Trauma Systems, Department of Global Public Health, Karolinska Institutet (15%)

2021– | Member of the Doctoral Board, Department of Global Public Health, Karolinska Institutet

2016– | Course Leader, Degree Project in Global Health, Karolinska Institutet

RESEARCH GRANTS AWARDED IN COMPETITION AS PRINCIPAL INVESTIGATOR

2021 | Combining Human and Artificial Intelligence to Improve Trauma Care Outcomes (Reg no. SLS-973387); June 2022 - June 2024; 200 000 SEK; Swedish Society of Medicine (Svenska Läkaresällskapets).

2020 | A Pilot Multi-center Cluster Randomized Trial to Compare The Effect of Trauma Life Support Training Programs on Patient and Provider Outcomes (Reg no. 2021-0048); December 2021 - December 2022; 220 000 SEK; Laerdal Foundation.

2020 | Does trauma life support training improve patient outcomes? Establishing a network of Swedish and Indian researchers (Reg no. 2020-03779); January 2021 - December 2022; 790 020 SEK; Swedish Research Council (Vetenskapsrådet).

2016 | Does institutional implementation of audit filters reduce mortality in adult trauma patients? (Reg no. 2016-02041); January 2017 - December 2021 (extended to July 2023 due to Covid-19); 4 000 000 SEK; Sweden Research Council (Vetenskapsrådet).

2016–2018 | Improving trauma triage; January 2017 - December 2019; 3 000 000 SEK; Swedish National Board of Health and Welfare (Socialstyrelsen).

PhD Supervision

Kelvin Szolnoky | Co-supervisor; Expected to defend in 2027; Department of Medical Epidemiology and Biostatistics, Karolinska Institutet.

Jonatan Attergrim | Main supervisor; Expected to defend in 2027; Department of Global Public Health, Karolinska Institutet.

Johanna Berg | Main supervisor; Expected to defend in 2024; Department of Global Public Health, Karolinska Institutet.

Lukas Berglund | Co-supervisor; Expected to defend in 2024; Department of Clinical Science, Innovation and Technology, Karolinska Institutet.

Uzma Rahim Khan | Main supervisor; Defended in October 2022; Department of Global Public Health, Karolinska Institutet.

Siddarth David | Main supervisor; Defended in May 2022; Department of Global Public Health, Karolinska Institutet.

LANGUAGE SKILLS

Swedish and English

REFERENCES

Available upon request

Signering av etikprövningsansökan

Grundansökan

Forskningshuvudman: Karolinska Institutet
Projekttitel: Effekter av träning i traumaomhändertagande på utfall hos vuxna traumapatienter: en klusterrandomiserad studie

I och med att ansökan undertecknas intygar du som är behörig företrädare följande:

- Att den information som lämnas i ansökan om etikprövning och samtliga medföljande bilagor är riktig och fullständig.
- Att verksamhetsansvariga i samtliga medverkande verksamheter är informerade om forskningsprojektets innehåll och utförande och att de har samtyckt till att delta i studien.
- Att du säkerställt att det i samtliga medverkande verksamheter finns resurser som garanterar forskningspersonernas säkerhet och integritet vid genomförandet av den forskning som beskrivs i ansökan.
- Att ansvarig forskare ges rätt att företräda huvudmannen i alla framtida kontakter med Etikprövningsmyndigheten som rör detta forskningsprojekt samt ansöka om ändringar i forskningsprojektet.
- Att du tagit del av Etikprövningsmyndighetens information om behandling av personuppgifter på myndighetens webbplats, www.etikprovning.se. Länk till informationen finns i sidfoten på startsidan.

BankID

Behörig företrädare har signerat.

Signerat av Marie Elisabet Klang Hasselberg 2024-11-15 10:06:51

Signering av etikprövningsansökan

Grundansökan

Forskningshuvudman: Karolinska Institutet
Projekttitel: Effekter av träning i traumaomhändertagande på utfall hos vuxna traumapatienter: en klusterrandomiserad studie

I och med att ansökan undertecknas intygar du som är ansvarig forskare följande:

- Att den information som lämnas i ansökan om etikprövning och samtliga medföljande bilagor är riktig och fullständig.
- Att verksamhetsansvariga i samtliga medverkande verksamheter är informerade om forskningsprojektets innehåll och utförande och att de har samtyckt till att delta i studien.
- Att du säkerställt att det i samtliga medverkande verksamheter finns resurser som garanterar forskningspersonernas säkerhet och integritet vid genomförandet av den forskning som beskrivs i ansökan.
- Att du tagit del av Etikprövningsmyndighetens information om behandling av personuppgifter på myndighetens webbplats, www.etikprovning.se. Länk till informationen finns i sidfoten på startsidan.

BankID

Ansvarig forskare har signerat.

Signerat av MARTIN GERDIN WÄRNBERG 2024-11-15 06:35:01

Avgiftsavisering

Etikprövningsmyndigheten har tagit emot din ansökan med titel Effekter av träning i traumaomhändertagande på utfall hos vuxna traumapatienter: en klusterrandomiserad studie om etikprövning. Ansökan har diarienummer 2024-07547-01 vilket alltid ska anges i framtida kontakter i ärendet.

Avgiften för ansökan, som är 5000 kronor, ska omgående betalas in enligt nedan:

- Inbetalning sker till bankgironummer 406-1107
- Vid inbetalning ska OCR-nummer 2024075470136 anges som referens.
- Inga andra bokstäver eller siffror får anges i raden för referens.

Först när avgiften har inkommit kommer vi att påbörja handläggningen. Avgiften ska vara myndigheten tillhanda senast 1 vecka efter att ansökan inkom. Om avgiften inte inkommit detta datum kan ansökan komma att avvisas.

Etikprövningsmyndigheten
Telefon: 010 - 475 08 00
Webbplats: www.etikprovning.se

BESLUT

2024-12-09

Sökande forskningshuvudman
Karolinska Institutet

Forskare som genomför projektet
Martin Knut Erik Filippus Gerdin Wärnberg

Projekttitel
Effekter av träning i traumaomhändertagande på utfall hos vuxna traumapatienter: en klusterrandomiserad studie

Uppgifter om ansökan
Ansökan inkom till Etikprövningsmyndigheten 2024-11-15 och blev valid 2024-11-20.

Etikprövningsmyndigheten beslutar enligt nedan.

BESLUT

Etikprövningsmyndigheten godkänner den forskning som anges i ansökan.

På Etikprövningsmyndighetens vägnar

Roy Johansson
Ordförande

Beslutet har fattats av följande personer:

Ordförande
Roy Johansson (Hovrättsråd)

Ledamöter med vetenskaplig kompetens
Charlotta Lundh (Medicinsk strålfysik, vetenskaplig sekreterare)
Daniel Giglio (Onkologi, föredragande)
Bert Andersson (Kardiologi)
Anette Ekström-Bergström (Professor i omvårdnad, Barnmorska, Sjuksköterska,Vårdvetenskap, reproduktiv, perinatal och sexuell hälsa, barnafödande, amning, hälsa)
Albert Gyllencreutz Castellheim (Barn- och vuxenanestesi-intensivvård, medfödda hjärtfel, RCTs, Läkemedelsstudier, Katastrofmedicin)
André Sadeghi (Audiologi)
Ann Thurin Kjellberg (Reproduktionsmedicin)
Eleonora Vestergren (Medicinsk strålningsfysik)

Ledamöter som företräder allmänna intressen
Mona-Lisa Dahlberg
Barbro Anita Gunnarsson
Kenneth Gustavsson
Kent Gunnar Olaisson
Elise Pilhem

Beslutet sänds till
Ansvarig forskare: Martin Knut Erik Filippus Gerdin Wärnberg
Forskningshuvudmannens företrädare: Marie Elisabet Klang Hasselberg