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Application

Gerdin Wärnberg, Martin

Information about applicant

Project leader: Martin Gerdin Wärnberg

Doctoral degree: 2015-11-27

Birthdate: 19880127

Academic title: Associate professor

Gender: Male

Employer: Karolinska Institutet

Administrating organisation: Karolinska Institutet

Project site: GPH (Institutionen för global folkhälsa)

Information about application

Call name: Research Grants Open call 2023 (Medicine and Health)

Type of grant: Grant for research time

Focus: Clinical environment

Call for proposals subject area: MH

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

Project start: 2024-01-01

Project end: 2028-12-31

Review panel applied for: MH-13, MH-06

Classification code: 30299. Other Clinical Medicine, 30302. Public Health, Global Health, Social Medicine and Epidemiology, 30301. Health Care Service and Management, Health Policy and Services and Health Economy

Keywords: Trauma life support training, Patient outcomes, Mortality, Morbidity, Stepped-wedge cluster randomised controlled trial

Project title (Swedish)

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

Project title (English)

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

Abstract and popular science description

Abstract (English)

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 stress the need for such trials.

We will conduct a batched stepped wedge cluster randomised controlled trial with the aim to compare the effects of ATLS® training with standard care on outcomes in adult trauma patients. Cluster will be hospitals in India. We will roll out the intervention of ATLS® training to 32 clusters organised in four batches. Within each batch, clusters will be randomised to one of eight implementation sequences. We expect a sample size of 6528 patients over five years.

This is a collaborative project between researchers and institutions in Sweden, India, and the United Kingdom. Our research will be important regardless of whether the results are positive or negative. If we show that ATLS® improves patient outcomes then ATLS® should be promoted to save lives and reduce morbidity. If we show that ATLS does not improve patient outcomes then this should impact how trauma life support training is delivered and new course concepts may be needed.

Popular science description (Swedish)

Varje år dör 4.5 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®, 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.

Deductible time

Deductible time

	Cause	Months
1	Other approved reason*	18
2	Other approved reason*	24
3	Parental leave	15
Total		57

Career age is a description of the time from your first doctoral degree until the last application day of the call. Your career age changes if you indicate deductible time due to a reason approved by the funder. For some calls there are restrictions in the allowed career age.

Special area

Special area

No focus area is available for this application

Planned use of research infrastructure

Planned use of research infrastructure

No

Other applications or grants

Are any of the items relevant to you?

Yes

Justification and explanation of the relationship between the different projects and/or applications

In addition to the current call, I will also apply for the following grants:
- Swedish Research Council Research Grants Open call in Medicine in Health. I will apply for this grant to cover project costs associated with this trial.
- Swedish Research Council Development Research. I will propose to assess the effectiveness of a low cost alternative to Advanced Trauma Life Support® using a design that is feasible under the funding constraints of that call.
- Laerdal Foundation Project support grant. I will apply for the same project idea as this call but for additional funding to allow longer follow up and higher resolution data collection.
- European Research Council Advanced and starting grants. Similar to the Laerdal Foundation Project support grant, I will apply for this grant to 1) allow for the inclusion of more clusters to power the trial for subgroup analyses, and 2) allow for longer follow up and higher resolution data collection.

Specification of clinical position

Describe in what way you fulfil the requirement for employment in health and medical care according to the call text.

I am employed as a resident in anaesthesia and intensive care at Function Perioperative Medicine and Intensive Care at Karolinska University Hospital in Solna. My employment level is 100%.

Ethical aspects: Legal and formal requirements

The research includes animal testing that requires ethical approval under the Animal Welfare Act (2018:1192)

No

The research includes studies on humans and/or biological material from humans and requires approval under the Act (2003:460) on ethical review of research relating to humans

Yes

The project is a drug trial and/or clinical study

Yes

The research includes the processing of personal data in accordance with the General Data Protection Regulation

Yes

Description of approvals and permits

Our project involves human participants and covers handling of personal data. We will conduct the research in India but we will store pseudonymised data on servers in Sweden and conduct the data analysis using these data. We will therefore require the following approvals:

Indian Health Ministry Screening Committee approval. This approval is required for health research in India involving foreign funding. We will apply for this approval during 2023 or early 2024 through our collaboration partner The George Institute for Global Health (TGI), which has extensive experience in applying for and being granted this approval for similar trials. This approval typically takes four months.

Ethical approval at each of the participating hospitals. We will apply for ethical approval from each of the participating hospitals, because India has no central ethical review authority with the mandate to clear projects across hospitals. We will apply for ethical approval from hospitals as they are found eligible for participation. TGI will coordinate these applications. Based on previous experiences these approvals take between four to six months.

Ethical approval in Sweden. We will apply for ethical approval from the The Swedish Ethical Review Authority, which is required for the handling of pseudonymised personal data in Sweden. This application will be coordinated by the principal investigator and is expected to take three months.

We will also register the handling of personal data with the Data Protection Officer at Karolinska Institutet.

Ethical considerations

Description of ethical considerations

How do your research questions and expected results measure up in relation to the ethical issues?
There are three main ethical issues with our research:

- Trauma patients constitute a vulnerable population because they often arrive in a state of emotional and physical distress with injuries and pain from injuries affecting their level of consciousness. They also often lack the protection of a proxy decision maker.
- It will not be possible for patients to opt out from being subjected to the intervention, because the intervention is delivered at the cluster level and involves training physicians in trauma life support. Therefore, as physicians cannot be expected to temporarily forget their training.
- We will apply for a waiver of informed consent from the ethical review boards at the participating hospitals. We do this because the target population will often have reduced decisional capacity at the time of data collection and the nature of the intervention is such that they can not refuse receiving it.

Regulations on medical research in Sweden and India allow such a waiver when the research is expected to generate knowledge that cannot be generated through research using informed consent, or the research is expected to directly benefit research participants. If the research is not expected to directly benefit research participants it is still allowed if the research is expected to generate knowledge that can directly benefit the patient population to which the participant belongs, and the research involves minimal risk.

Our research measure up to these issues for the following reasons. First, it cannot be conducted using informed consent because the cohort of patients with severe trauma is the group most likely to benefit from improvements in early management and it is therefore crucial to include this population. Second, the research can directly benefit the participants during the intervention phase if ATLS is found to improve patient outcomes. 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.

What (direct) risks (physical, mental, or integrity) will research persons or animals be exposed to?
The direct risks includes integrity violations and data leakage. We will mitigate these risks by employing rigorous data collection and storage mechanisms.

What long-term risks may arise from the research? Is there any risk that the research may be used in a way that is detrimental to animals, nature/the environment, or society (whole or parts of the same) in other respects?
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.

Is the research expected to contribute to other values over and above the knowledge gain? If so, to whom?
In addition to the knowledge gain, our research may directly benefit the participants enrolled during the intervention phase in each hospital.

How do you weigh up the risks (in particular short-term risks) against the value (which is often more long-term) of the research?
We assess the short term risks as minimal, because the intervention involves training physicians in a well established trauma life support programme and the data collection rely mostly on data from participants' hospital records. We will not perform any invasive measurements or procedures as part of the data collection. The short term risks of integrity violations and data leakage are weighed up by the potential direct benefit for the participants in the intervention phase and by the potential for improved care for the trauma patient population.

Sex and gender perspectives

Sex and gender perspectives in the proposed research

Yes

Motivate your answer

The sex and gender perspectives are integral parts of our research. We have previously shown that almost 80% of both patients who present and patients who are admitted with trauma in the setting of our proposed research are male. We have also shown that female and male patients have similar odds of early and late mortality after adjusting for potential confounders. In yet unpublished data, we find that old-aged females (60 years and above) and middle-aged men (33-59 years) report the lowest health status, while middle-aged females had the highest odds of reporting problems across the functional domains. In qualitative interviews with trauma patients after discharge from hospital we find that females and males face different challenges, especially regarding self care and daily activities.

These previous findings indicate that we can expect outcomes, and particularly secondary non-mortality outcomes, to differ between females and males. In our proposed trial we therefore take account of sex and gender perspectives in two ways. First, we will adjust for sex in our fully adjusted covariate analysis. This will allow us to identify and discuss the effect of patient sex on the trial outcomes. Second, we will perform prespecified subgroup analyses in females and males respectively. These subgroup analyses will allow us to explore potential heterogeneity in the intervention effect in females and males. These subgroup analyses will unfortunately need to be explorative and hypothesis generating, as it is beyond the limits of the funding available within this call for these analyses to achieve the same power as the main analysis.

Research plan

See following page for attachment

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

1 Purpose and aims

Trauma is a massive global health issue.[1,2] Many training programmes have been developed to help physicians in the initial management of trauma patients.[3–6] Advanced Trauma Life Support® (ATLS®) is the most popular of these programmes and have been used to train over one million physicians worldwide.[7] Despite its widespread use, there are no controlled trials showing that ATLS® improves patient outcomes.[3,4,6] Multiple systematic reviews emphasise the need for such trials.[3,4,6] Therefore, we will conduct a cluster randomised trial with the aim of comparing the effects of ATLS® training with standard care on outcomes in adult trauma patients.

2 State-of-the-Art

Each year, 4.5 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.[8] Traumatic brain injury and exsanguination are the most common causes of trauma deaths.[9,10] 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.[9,11]

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.[3–6] 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.[7] In the US and many other countries training in ATLS® is virtually mandatory for trauma care physicians.[12] Uptake in low- and middle income countries (LMIC) has been slow, potentially due to high costs.[5]

There are three randomised controlled studies showing that ATLS® improves knowledge and clinical skills,[13–15] but there are no randomised controlled trials or high-quality quasi-experimental trials indicating that ATLS® improves patient outcomes.[3,4,6] We conducted an updated systematic review for this application (Text box 1) and estimated a pooled risk ratio of 0.82 (95% CI 0.60; 1.11) from ten heterogeneous (I^2 0.91) retrospective or small studies on the effect of ATLS on mortality (Figure 1).[16–25] This shows that the evidence that ATLS® has an effect on mortality is weak. No study assessed functional outcomes.

Text box 1: 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.

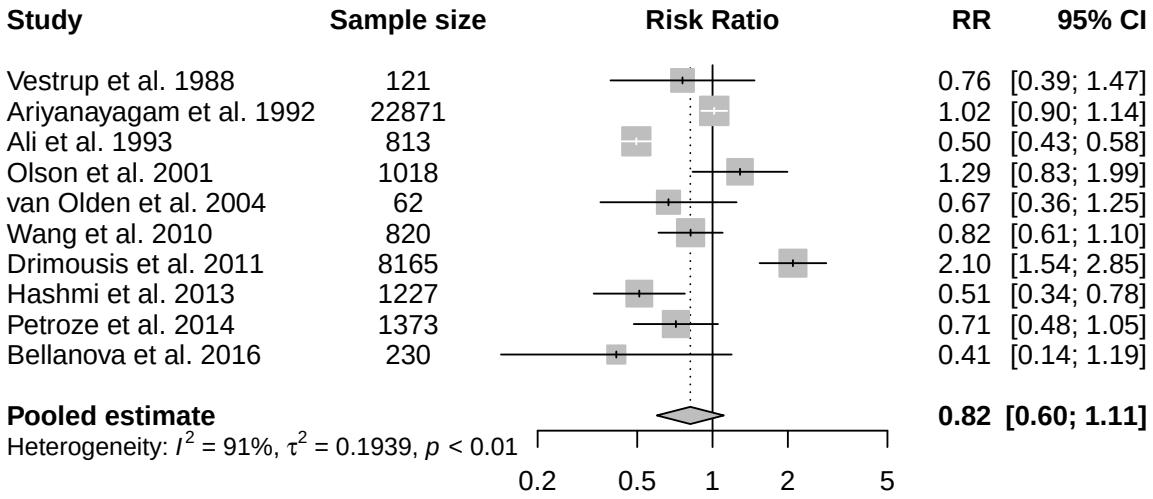

Figure 1: Summary of the systematic review conducted for this application. Abbreviations: CI Confidence Interval, RR Risk Ratio.

3 Significance and scientific novelty

We propose an ambitious but high-yield project that will result in the first robust evidence on the effects of ATLS® on patient outcomes since the programme was introduced. We advance the trauma research frontier by conducting large-scale research on a complex system intervention and move beyond the prevailing focus on retrospective research.[16–25] Systematic reviews call for cluster randomised or quasi-experimental trials in settings where ATLS® or similar programmes are not routinely taught.[3,4,6] Our findings will be important regardless of whether they are positive or negative. If ATLS® improves patient outcomes it should be further promoted. If ATLS® does not improve patient outcomes then trauma life support training needs to change.

4 Preliminary and previous results

This application was developed jointly by the parties participating in the Trauma life support training Effectiveness Research Network (www.tern.network), funded by a Swedish Research Council Network Grant (Dnr. 2020-03779). We have conducted multicentre trauma research in India since 2013 (www.titco.org), and identified opportunities for improvement in early trauma care potentially amendable with trauma life support training.[9]

We base this application on 1) data collected in our previous work, including a trial on the effectiveness of trauma audit filters (ClinicalTrials.gov NCT03235388) that ends this year and is funded by the Swedish Research Council (Dnr. 2016-02041) and 2) a pilot cluster randomised controlled trial (ClinicalTrials.gov NCT05417243) that we conducted 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.[26]

We have collected data from 35970 patients across 13 hospitals, out of which eight hospitals and 13979 patients fit the eligibility criteria of this trial. Among those eligible the average in-hospital mortality is 25%. Out of these patients, 81% are males and 19% are females. Our pilot study enrolled 375 patients from seven hospitals across India (unpublished data) and shows that it is feasible to conduct the proposed trial with a high recruitment rate (78%), low loss to follow-up rate (1%), and low missingness in key variables (mean 1%).

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.

5 Project description

5.1 Theory and method

We report our research plan according to the Consolidated Standards Of Reporting Trials (CONSORT) extension for stepped-wedge cluster randomised controlled trials.[27] The trial will be registered with the Clinical Trials Registry of India and ClinicalTrials.gov.

5.1.1 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.[28] Each cluster will be a tertiary hospital in India. We will conduct this trial in India because of 1) our established collaboration with Indian institutions and experience in conducting multicentre studies in this setting, and 2) physicians in India are 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 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.

5.1.2 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.[29] In this trial, the number of clusters is limited due to the constraints of the 1) available budget and time frame of this call and 2) 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.[30]

5.1.3 Participants

Because this is a cluster randomised trial, we have eligibility criteria both on the cluster, i.e. hospital, and individual patient levels.

Clusters must meet the following criteria:

- tertiary hospitals;
- 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;
- provides general surgery, neurosurgery, imaging and blood banking services around the clock; and
- no more than 25% of initial trauma care providers trained in any trauma life support programme.

Patients participants must meet the following criteria:

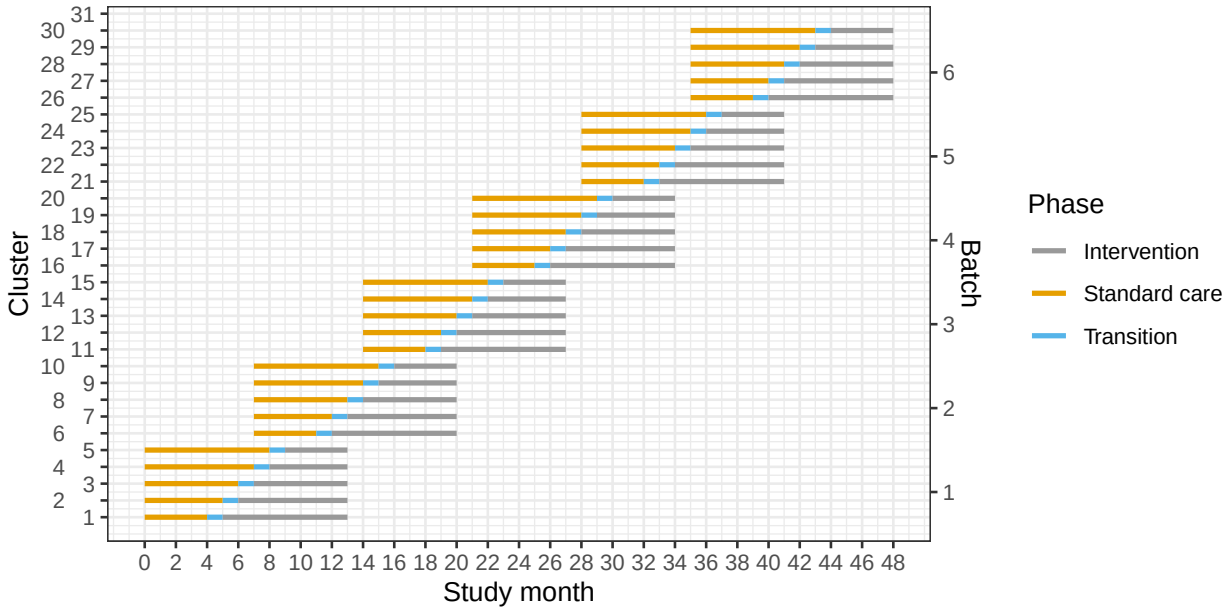

Figure 2: Trial design. Lines represent the duration of patient enrolment across clusters and phases. Clusters will be sequentially allocated to a batch based on when they enter the study. Within each batch clusters will then be randomised to an intervention implementation sequence.

- age of at least 15 years;
- 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;
- transferred from the emergency department of a participating hospital to another hospital for admission; and
- trauma occurred less than 48 hours before arrival at the hospital.

5.1.4 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. We will train the number of physicians needed to reach the required patient sample size.

Advanced Trauma Life Support® (ATLS®)[7] 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.

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.

5.1.5 Outcomes

We chose outcomes that we judged as clinically important and that patients, their caregivers and community representatives perceived as important in our interviews with them.

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. We chose this outcome as the primary outcome because it is an outcome of clinical and patient importance with very low missing data rates (1%) in our pilot study. We will also be able to compare our findings with previous research.

Secondary outcomes will be as follows:

- all cause mortality within 24 hours, 30 days, and three months of arrival at the emergency department;
- 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;
- poor functional outcome within seven days of discharge, and at 30 days and three months of arrival at the emergency department, assessed using the EQ5D3L domains of mobility, self-care, usual activities, and pain/discomfort, with poor functional outcome defined as being confined to bed, unable to bath or dress oneself, unable to perform usual activities, or having extreme pain or discomfort;
- return to work at 30 days and three months after arrival at the emergency department; and
- in-hospital pulmonary, septic, or renal complications.

5.1.6 Randomisation and blinding

We will assign clusters to batches as they are found to be eligible and receive ethical approval, and will randomise the clusters to intervention implementation sequences within batches. Randomisation will be stratified by geographical region and anticipated cluster size. The Karolinska Trial Alliance will perform the randomisation and conceal the allocation sequence as an independent consultancy. We will not be able to blind patient participants, physicians, or clinical research coordinators conducting the data collection to the intervention; however, we will blind data analysts and the data and security monitoring board during interim analyses.

5.1.7 Data collection and management

Clinical research coordinators will collect data, screen patients using emergency department records, and obtain informed consent for post-discharge follow-up. Paper-based CRFs will be securely stored on-site and uploaded to project servers using a VPN with two-factor authentication. Access is granted by the project PI or authorized delegates. Metadata will be publicly accessible via a persistent DOI, and anonymised data will be released upon project completion. The data management plan is published and was reviewed by Karolinska Institutet (https://doi.org/10.5281/zenodo.7748764).

5.1.8 Quality assurance and monitoring

We will monitor the trial according to a prespecified monitoring plan, with the aim to ensure that participants' rights, safety, and well-being are met, that the trial is carried out according to the protocol and that data are collected, documented, and reported according to the International Conference on Harmonisation - Good Clinical Practice and applicable ethical and regulatory requirements. A data and security monitoring board, comprising four external members, will 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.

5.2 Time plan and implementation

This project will run for five years (see Figure 3). During the first year we will obtain the necessary approvals and start data collection in the first batch. During the following years we will enrol clusters and obtain approvals for each subsequent batch. The final patient follow-up will be in October 2028. The main risks and our corresponding mitigation plans are:

- **delays in obtaining approvals**: be proactive and start necessary processes, for example submissions to ethical review boards, long before the study is planned to start in each centre;
- **delays in cluster recruitment**: approach potential clusters long before the intended study start, leveraging our considerable existing networks to (the hospitals that will participate in the first batch are already finalised);
- **lower than expected enrolment rates**: perform careful on-site evaluations before a cluster is formally enrolled to avoid lower than expected enrolment rates.

There is also the risk of unforeseen global events like the COVID-19 pandemic. While we cannot mitigate this risk we have limited its potential impact on our trial by adopting the batched stepped-wedge design, which makes it feasible to pause and resume the trial between batches without compromising its quality.

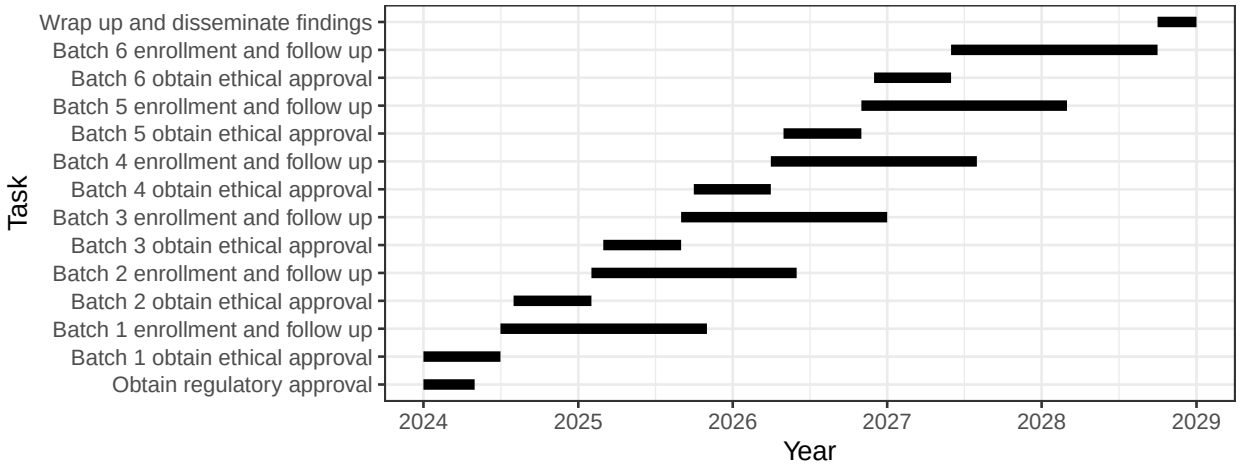

Figure 3: Project time plan with key tasks

5.3 Project organisation, international and national collaboration

This is a collaborative project between researchers, clinicians, and institutions in Sweden, India, and the United Kingdom, which will be led by Karolinska Institutet (KI) in Sweden and The George Institute for Global Health (TGI) in India. KI is the university accounting for the largest share of all academic medical research in Sweden. TGI is a leading independent medical research institute with extensive experience in conducting large scale clinical trials across India. KI will be the trial sponsor, maintain the overall responsibility for the trial, store the trial data and conduct the data analyses. TGI will coordinate the project activities in India, including approvals, data collection, ATLS® training, and monitoring, with a full-time team: a project manager, a clinical research associate, and five clinical research coordinators.

5.3.1 Principal investigator

Martin Gerdin Wärnberg is an Associate Professor of Clinical Epidemiology at KI. Martin has led multicentre observational and interventional trauma research in India for 10 years. He will coordinate the project and oversee data management, analysis and reporting. His activity level will

be 30%. Several of Martin's large projects are coming to an end during 2023, which is why he will be able to dedicate 30% of his research activities to this trial. Except for the pilot study leading up to this application, Martin has no previous experience conducting cluster randomised controlled trials, but this is compensated for by the team of participating researchers.

5.3.2 Participating researchers

This team of participating researchers will provide methodological expertise and experience in conducting large scale research, including cluster randomised controlled trials in India and elsewhere, as well as clinical trauma care expertise.

Vivekanand Jha is a Professor and the Executive Director of the George Institute for Global Health India. He has led many high-impact clinical trials including cluster randomised trials and contributes with his expertise in managing similar large scale trials in India. **Anita Gadgil** is Professor and Head of Surgery Department at the Bhabha Atomic Research Centre Hospital in Mumbai and headed the WHO Collaboration Centre for Research on Surgical Care Delivery in LMIC. Anita will contribute knowledge on care delivery and patient focused outcome measures research. **Li Felländer-Tsai** is a Professor of Orthopaedic Surgery at KI and Senior Consultant at the Karolinska University Hospital. Li will contribute her experience of delivering and studying training interventions. **Lovisa Strömmer** is a trauma surgeon and Senior Consultant in Surgery at the Karolinska University Hospital, as well as Associate Professor of Surgery at KI. Lovisa will contribute with her substantial clinical trauma expertise and experience in researching trauma outcomes. **Karla Hemming** is a Professor of Biostatistics at the University of Birmingham where she leads a research programme related to stepped-wedge trials. Karla is an international expert in stepped-wedge trials and will provide input on design and analysis.

5.4 Project members

In addition to the participating researchers, this trial will be possible because of the extensive networks and key skills of its project members, all of whom all will be directly involved in the research project and developed this application.

Makhan Lal Saha is a visiting consultant at M R Bangur Hospital Kolkata and the former Professor and Head of the Department of General Surgery at IPGME&R/SSKM Hospital in Kolkata. He is also the immediate past president of the Association of Surgeons of India West Bengal state chapter. **Girish Bakhshi** is presently working as a professor and is in charge of the trauma services of the Department of Surgery, Grant Government Medical college & Sir J.J.Group of Hospitals, Mumbai, India. **Shamita Chatterjee** is a Professor of General Surgery at IPGME&R/SSKM Hospital in Kolkata with a special interest in trauma management. She teaches and examines General Surgery and Trauma. **Rajdeep Singh** is a Professor of Surgery at Maulana Azad Medical College (MAMC), New Delhi. He practices as a general surgeon and is the principal investigator of several trauma research projects. **Deepa Kizhakke Veetil** is a general surgeon and researcher presently working with Manipal Hospitals in Delhi. She has a Masters in Trauma Sciences and developed the standard treatment guidelines for major trauma for the Government of India. **Monty Khajanchi** is a faculty member in general and trauma surgery at a public university hospital in Mumbai. He worked with the Government of India to develop standard treatment guidelines for trauma care and is a consultant at the WHO for surgical and related services. **Kapil Dev Soni** is a faculty member in Critical and Intensive Care at JPN Apex Trauma Center, All India Institute of Medical Sciences, New Delhi. He has completed a fellowship in designing clinical studies and evidence-based medicine and has contributed to the of standard treatment guidelines for trauma care. **Anurag Mishra** is a surgeon and Associate Professor working at MAMC, New Delhi. **Johanna Berg**, who is an Emergency Medicine physician in Malmo and a PhD candidate at KI, developed the data management

plan. **Siddarth David**, a public heath researcher with a PhD from KI, has researched equity in health care access in communities for more than a decade.

5.5 Data analysis and statistics

5.5.1 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. All secondary outcomes will be interpreted with due consideration for how all are affected by the intervention. We will use a two-sided significance level of 5% and estimate 95% confidence intervals. We will report time-adjusted within-cluster correlations for all outcomes with 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. Additional subgroup analyses will include age, sex, and clinical cohorts with blunt multisytem trauma, penetrating trauma, and severe isolated traumatic brain injury.

5.5.2 Analysis models

All analyses will consider the clustered nature of the design. For the primary and binary secondary outcomes, we will use mixed effects binomial regression with a log-link to estimate the relative risk, and a binomial model with identity link to estimate the risk difference.[31] We will develop non-convergence plans. We will use the Kenward and Roger small sample correction to correct for the potential inflation of the type-I error caused by a small number of clusters. We will adjust for temporal confounding because the design is a stepped-wedge trial. To allow for the randomisation by batches, a different secular trend will be included for each batch. We will use similar model-based approaches for continuous secondary outcomes. In a sensitivity analysis we will explore whether models with more complicated correlation structures are a better fit. 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 that might be plausible.

5.5.3 Additional sensitivity analyses

To additionally explore whether 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 whether the results are sensitive to the assumption of no intervention by cluster interaction. We will also extend models 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. A fully adjusted covariate analysis will additionally adjust for age, sex, mechanism of injury, and trauma severity, which are individual-level covariates of known prognostic importance.

5.5.4 Power analysis

With 30 clusters 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 from 20% under standard care to 15% after ATLS® training. 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,[32,33] and a CAC of 0.9 but considered sensitivity across the range 0.8-1.0, based on our pilot study and current guidance.[34–36] 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.

5.6 Equipment (not applicable)

5.7 Need for research infrastructure (not applicable)

5.8 Independent line of research (not applicable)

5.9 Clinical significance

We will establish the effects of ATLS®, the most widely used trauma life support training programme worldwide, on patient outcomes. The results of our trial are directly applicable to clinical trauma care practice and will influence how trauma life support is trained globally, regardless of its outcome. In the case of a positive trial with ATLS® improving outcomes over standard care this programme should be promoted and ways to increase its uptake should be explored. In the case of a negative trial new ways to perform trauma life support training are needed.

6 References

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27. Hemming, K. *et al.* Reporting of stepped wedge cluster randomised trials: Extension of the consort 2010 statement with explanation and elaboration. *BMJ* k1614 (2018).
28. Hemming, K. *et al.* The stepped wedge cluster randomised trial: Rationale, design, analysis, and reporting. *BMJ* **350**, h391–h391 (2015).
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30. Kasza, J. *et al.* The batched stepped wedge design: A design robust to delays in cluster recruitment. *Stat Med* **41**, 3627–3641 (2022).
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Activity level in the project

Activity level

30% - flat rate amount: 1 510 000 sek/year

Justification of the budget applied for

Justification of the budget applied for

The primary costs that I intend to cover within the framework for this grant budget are:

- my research time, corresponding to 30% of full time for five years;
- the salary of one PhD-student, full-time, for three years;
- the salary of one research assistant, corresponding to 20% of full time for three years;
- the salary of one postdoctoral researcher, full-time, for two years; and
- travel and accommodation during research visits to trial sites and collaborators.

I have applied for the remaining project costs related to project management, data collection, trial monitoring and ATLS® training in my application for the Swedish Research Council Project Grant in Medicine and Health.

Other funding for this project

Funder	Applicant/project leader	Type of grant	Status	Reg no or equiv.
1 Swedish Research Council	Martin Gerdin Wärnberg	Project Grant	Applied	0
Total				

	2024	2025	2026	2027	2028	Total
1	2,466,000	2,460,000	2,464,000	2,386,000	2,360,000	12,136,000
Total	2,466,000	2,460,000	2,464,000	2,386,000	2,360,000	12,136,000

Applicant's publication list

See following page for attachment

Selection of publications

1. David S, Roy N, Lundborg CS, **Gerdin Wärnberg M**, Solomon H. 'Coming home does not mean that the injury has gone'-exploring the lived experience of socioeconomic and quality of life outcomes in post-discharge trauma patients in urban India. *Glob Public Health*. 2022 Nov;17(11):3022-3042. doi: 10.1080/17441692.2022.2036217.

   In this qualitative interview study, we found that participants had needs unmet by the health-care system even late after the injury. I assisted with designing the study, interpreting the findings, and provided input during the writing of the paper.

2. Pendleton AA, Sarang B, Mohan M, Raykar N, **Gerdin Wärnberg M**, Khajanchi M, Dharap S, Fitzgerald M, Sharma N, Soni KD, O'Reilly G, Bhandarkar P, Misra M, Mathew J, Jarwani B, Howard T, Gupta A, Cameron P, Bhoi S, Roy N. A cohort study of differences in trauma outcomes between females and males at four Indian Urban Trauma Centers. *Injury*. 2022 Sep;53(9):3052-3058. doi: 10.1016/j.injury.2022.07.022.

   This paper shows that female and male trauma patients have similar odds of mortality within 24 hours and 30 days after arrival to hospital in the setting of our proposed trial. I conducted part of the data analysis and provided input on the write up of the paper.

3. Berg J, Alvesson HM, Roy N, Ekelund U, Bains L, Chatterjee S, Bhattacharjee PK, David S, Gupta S, Kamble J, Khajanchi M, Lal P, Malhotra V, Meher R, Mishra A, Mohan LN, Petzold M, Saxena R, Shrivastava P, Singh R, Soni KD, Sural S, **Gerdin Wärnberg M**. Perceived usefulness of trauma audit filters in urban India: a mixed-methods multicentre Delphi study comparing filters from the WHO and low and middle-income countries. *BMJ Open*. 2022 Jun 9;12(6):e059948. doi: 10.1136/bmjopen-2021-059948.

   This paper is part of an interrupted time series trial, funded by the Swedish Research Council (Dnr 2016-02041), assessing the effectiveness of implementing trauma audit filters on mortality in adult trauma patients in urban India. I was the senior author on this paper.

4. **Gerdin Wärnberg M**, Berg J, Bhandarkar P, Chatterjee A, Chatterjee S, Chintamani C, Felländer-Tsai L, Gadgil A, Ghag G, Hasselberg M, Juillard C, Khajanchi M, Kizhakke Veetil D, Kumar V, Kundu D, Mishra A, Patil P, Roy N, Roy A, David S, Singh R, Solomon H, Soni KD, Strömmer L, Tandon M; Trauma life support training Effectiveness Research Network (TERN) collaborators. A pilot multicentre cluster randomised trial to compare the effect of trauma life support training programmes on patient and provider outcomes. *BMJ Open*. 2022 Apr 18;12(4):e057504. doi: 10.1136/bmjopen-2021-057504.

   This is the published protocol of the pilot study that was part of our Swedish Research Council Network Grant (Dnr. 2020-03779, www.tern.network, ClinicalTrials.gov NCT05417243), and on which the current application is based. I led the planning and writing up of this paper.

5. David SD, Aroke A, Roy N, Solomon H, Lundborg CS, **Gerdin Wärnberg M**. Measuring socioeconomic outcomes in trauma patients up to one year post-discharge: A systematic review and meta-analysis. *Injury*. 2022 Feb;53(2):272-285. doi: 10.1016/j.injury.2021.10.012.

   We found than one-third (36%) of patients had not returned to work even a year after discharge. Those who did return to work took more than 3 months to do so. We also found that older adults and females tended to have poorer outcomes. I was the senior author on this paper.

6. David SD, Roy N, Solomon H, Lundborg CS, **Gerdin Wärnberg M**. Measuring post-discharge

socioeconomic and quality of life outcomes in trauma patients: a scoping review. *J Patient Rep Outcomes*. 2021 Aug 9;5(1):68. doi: 10.1186/s41687-021-00346-6.

We identified quality of life, return to work, social support, cost, and participation as the main outcomes studied in post-discharge trauma patients, which was important in finalising the outcomes for our proposed trial. I was the senior author on this paper.

7. Sarang B, Bhandarkar P, Raykar N, O'Reilly GM, Soni KD, **Gerdin Wärnberg M**, Khajanchi M, Dharap S, Cameron P, Howard T, Gadgil A, Jarwani B, Mohan M, Bhoi S, Roy N. Associations of On-arrival Vital Signs with 24-hour In-hospital Mortality in Adult Trauma Patients Admitted to Four Public University Hospitals in Urban India: A Prospective Multi-Centre Cohort Study. *Injury*. 2021 Feb 26:S0020-1383(21)00178-9. doi: 10.1016/j.injury.2021.02.075.

   This paper confirms the associations of vital sign derangements and early mortality in the setting of the proposed trial, and highlights the need for interventions that target the causes of these derangements. I assisted in the analysis and the interpretation of findings, and provided input during the writing of the paper.

8. Khajanchi M, Kumar V, Wärnberg Gerdin L, Roy N, **Gerdin Wärnberg M**. Prevalence of a Definitive Airway in Severe Traumatic Brain Injury patients received at four Urban Public University Hospitals in India – a Cohort Study. *Inj Prev*. 2019 Oct;25(5):428-432. doi: 10.1136/injuryprev-2018-042826.

   This paper shows that airway management represent a major opportunity for improvement in the setting of the proposed trial, as only 15% of patients with a severe traumatic brain injury who were transferred between hospitals had a definitive airway placed before transfer. I was the senior author on this paper.

9. Mansourati M, Kumar V, Khajanchi M, Saha ML, Dharap S, Seger R, **Gerdin Wärnberg M**. Mortality following surgery for trauma in an Indian trauma cohort. *Br J Surg*. 2018.

   This paper shows that mortality following trauma surgery is as high as 23% in the setting of the proposed trial, and that abdominal and vascular surgery are associated with the highest risks. I was the senior author on this paper.

10. Roy N, **Gerdin M**, Ghosh S, Gupta A, Kumar V, Khajanchi M, et al. 30-Day In-hospital Trauma Mortality in Four Urban University Hospitals Using an Indian Trauma Registry. *World J Surg*. 2016 Jun 24;40(6):1299–307.

    We showed that the 30-day mortality in adult trauma patients in the setting of our proposed was around 20%. I assisted during data analysis and provided input during the writing of the paper.

Relevant publications from 2015–2023

Peer-reviewed original articles

1. Aroke A, Rohini D, Sarang B, David S, O'Reilly G, Raykar N, Khajanchi M, Attergrim J, Dev Soni K, Naveen S, Mohan M, Gadgil A, Roy N, **Gerdin Wärnberg M**. Profile and Triage Validity of Trauma Patients Triaged Green: A Prospective Cohort Study from a Secondary Care Hospital in India. Accepted *BMJ Open*. 2023 Mar.
2. David S, Roy N, Lundborg CS, **Gerdin Wärnberg M**, Solomon H. 'Coming home does not mean that the injury has gone'-exploring the lived experience of socioeconomic and quality of life outcomes in post-discharge trauma patients in urban India. *Glob Public Health*. 2022

Nov;17(11):3022-3042. doi: 10.1080/17441692.2022.2036217.
3. Pendleton AA, Sarang B, Mohan M, Raykar N, **Gerdin Wärnberg M**, Khajanchi M, Dharap S, Fitzgerald M, Sharma N, Soni KD, O'Reilly G, Bhandarkar P, Misra M, Mathew J, Jarwani B, Howard T, Gupta A, Cameron P, Bhoi S, Roy N. A cohort study of differences in trauma outcomes between females and males at four Indian Urban Trauma Centers. *Injury*. 2022 Sep;53(9):3052-3058. doi: 10.1016/j.injury.2022.07.022.
4. Khan UR, Razzak JA, Jooma R, **Gerdin Wärnberg M**. Association of age and severe injury in young motorcycle riders: A cross-sectional study from Karachi, Pakistan. *Injury*. 2022 Sep;53(9):3019-3024. doi: 10.1016/j.injury.2022.04.017.
5. Kayambankadzanja RK, Schell CO, **Gerdin Wärnberg M**, Tamras T, Mollazadegan H, Holmberg M, Alvesson HM, Baker T. Towards definitions of critical illness and critical care using concept analysis. *BMJ Open*. 2022 Sep 5;12(9):e060972. doi: 10.1136/bmjopen-2022-060972.
6. Berg J, Alvesson HM, Roy N, Ekelund U, Bains L, Chatterjee S, Bhattacharjee PK, David S, Gupta S, Kamble J, Khajanchi M, Lal P, Malhotra V, Meher R, Mishra A, Mohan LN, Petzold M, Saxena R, Shrivastava P, Singh R, Soni KD, Sural S, **Gerdin Wärnberg M**. Perceived usefulness of trauma audit filters in urban India: a mixed-methods multicentre Delphi study comparing filters from the WHO and low and middle-income countries. *BMJ Open*. 2022 Jun 9;12(6):e059948. doi: 10.1136/bmjopen-2021-059948.
7. Banerjee N, Sharma N, Soni KD, Bansal V, Mahajan A, Khajanchi M, **Gerdin Wärnberg M**, Roy N. Are home environment injuries more fatal in children and the elderly? *Injury*. 2022 Jun;53(6):1987-1993. doi: 10.1016/j.injury.2022.03.050.
8. Khan UR, Razzak J, **Gerdin Wärnberg M**. Association of adolescents' independent mobility with road traffic injuries in Karachi, Pakistan: a cross-sectional study. *BMJ Open*. 2022 Mar 22;12(3):e057206. doi: 10.1136/bmjopen-2021-057206.
9. David SD, Aroke A, Roy N, Solomon H, Lundborg CS, **Gerdin Wärnberg M**. Measuring socioeconomic outcomes in trauma patients up to one year post-discharge: A systematic review and meta-analysis. *Injury*. 2022 Feb;53(2):272-285. doi: 10.1016/j.injury.2021.10.012.
10. Sarang B, Raykar N, Gadgil A, Mishra G, **Gerdin Wärnberg M**, Rattan A, Khajanchi M, Soni KD, Mohan M, Sharma N, Kumar V, Kv D, Roy N; Towards Improved Trauma Care Outcomes TITCO-India. Outcomes of Renal Trauma in Indian Urban Tertiary Healthcare Centres: A Multicentre Cohort Study. *World J Surg*. 2021 Aug 21. doi: 10.1007/s00268-021-06293-z.
11. Larsson A, Berg J, Gellerfors M, **Gerdin Wärnberg M**. The advanced machine learner XGBoost did not reduce prehospital trauma mistriage compared with logistic regression: a simulation study. *BMC Med Inform Decis Mak*. 2021 Jun 21;21(1):192. doi: 10.1186/s12911-021-01558-y.
12. Sarang B, Bhandarkar P, Raykar N, O'Reilly GM, Soni KD, **Gerdin Wärnberg M**, Khajanchi M, Dharap S, Cameron P, Howard T, Gadgil A, Jarwani B, Mohan M, Bhoi S, Roy N. Associations of On-arrival Vital Signs with 24-hour In-hospital Mortality in Adult Trauma Patients Admitted to Four Public University Hospitals in Urban India: A Prospective Multi-Centre Cohort Study. *Injury*. 2021 Feb 26:S0020-1383(21)00178-9. doi: 10.1016/j.injury.2021.02.075.
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14. Henriksson M, D. Saulnier, D, Berg J, **Gerdin Wärnberg M**. The transfer of clinical prediction models for early trauma care had uncertain effects on mistriage. *Journal of Clinical Epidemiology*. Dec 2020; 120:66-73.
15. Wärnberg Gerdin L, Khajanchi M, Kumar V, Roy N, Saha ML, Soni KD, **Gerdin Wärnberg M**. Comparison of emergency department trauma triage performance of clinicians and clinical

prediction models: a cohort study in India. *BMJ Open*. 2020 Feb 1;10(2):e032900.
16. Laytin AD, Clarke D, **Gerdin Wärnberg M**, Kong VY, Bruce JL, Laing G, et al. The search for a simple injury score to reliably discriminate the risk of in-hospital mortality in South Africa. *Surgery*. 2020 Feb 21;
17. Kizhakke Veetil D, Kumar V, Khajanchi M, **Gerdin Wärnberg M**. A multicentre observational cohort study of the 24 hour and 30 day in hospital mortality of pediatric and adult trauma patients - an Indian urban tertiary care perspective. *J Pediatr Surg*. 2019 Jul;54(7):1421-1426. doi: 10.1016/j.jpedsurg.2018.10.101.
18. Attergrim J, Claeson A, Dharap S, Gupta A, Khajanchi M, Kumar V, Sterner M, **Gerdin Wärnberg M**. Predicting mortality with the international classification of disease injury severity score using survival risk ratios derived from an Indian trauma population: a cohort study. *PLoS One*. June 27, 2018.
19. Sterner M, Claeson A, Attergrim J, Khajanchi M, Kumar V, **Gerdin Wärnberg M**. Both the multiplicative and single-worst-injury international classification of diseases injury severity score (ICISS) underperform in urban Indian hospitals. *Trauma*. June 2018.
20. Khajanchi M, Kumar V, Wärnberg Gerdin L, Roy N, **Gerdin Wärnberg M**. Prevalence of a Definitive Airway in Severe Traumatic Brain Injury patients received at four Urban Public University Hospitals in India – a Cohort Study. *Inj Prev*. 2019 Oct;25(5):428-432. doi: 10.1136/injuryprev-2018-042826.
21. Claeson A, Sterner M, Attergrim J, Khajanchi M, Kumar V, Saha ML, **Gerdin Wärnberg M**. Assessment of the predictive value of ICISS for trauma mortality in urban India. *Journal of Surgical Research*. 2018;229:357—64.
22. Mansourati M, Kumar V, Khajanchi M, Saha ML, Dharap S, Seger R, **Gerdin Wärnberg M**. Mortality following surgery for trauma in an Indian trauma cohort. *Br J Surg*. 2018.
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24. Massenburg BB, Veetil DK, Raykar NP, Agrawal A, Roy N, **Gerdin M**. A systematic review of quantitative research on traumatic brain injury in India. *Neurol India*. 2016;65(2):305–14.
25. Roy N, **Gerdin M**, Schneider E, Kizhakke Veetil DK, Khajanchi M, Kumar V, et al. Validation of international trauma scoring systems in urban trauma centres in India. *Injury*. 2016 Nov;47(11):2459–64.
26. **Gerdin M**, Roy N, Felländer-Tsai L, Tomson G, von Schreeb J, Petzold M, et al. Traumatic transfers: calibration is adversely affected when prediction models are transferred between trauma care contexts in India and the United States. *J Clin Epidemiol*. 2016 Jun;74:177–86.
27. Roy N, **Gerdin M**, Ghosh S, Gupta A, Kumar V, Khajanchi M, et al. 30-Day In-hospital Trauma Mortality in Four Urban University Hospitals Using an Indian Trauma Registry. *World J Surg*. 2016 Jun 24;40(6):1299–307.
28. **Gerdin M**, Roy N, Khajanchi M, Kumar V, Felländer-Tsai L, Petzold M, et al. Validation of a novel prediction model for early mortality in adult trauma patients in three public university hospitals in urban India. *BMC Emerg Med*. 2016 Dec 22;16(1):15.

Peer-reviewed conference contributions, the results of which are not included in other publications

NA

Peer-reviewed edited volumes

NA

Research review articles

1. Kapanadze G, Berg J, Sun Y, **Gerdin Wärnberg M**. Facilitators and barriers impacting in-hospital Trauma Quality Improvement Program (TQIP) implementation across country income levels: a scoping review. *BMJ Open*. 2023 Feb 17;13(2):e068219. doi: 10.1136/bmjopen-2022-068219.
2. David SD, Roy N, Solomon H, Lundborg CS, **Gerdin Wärnberg M**. Measuring post-discharge socioeconomic and quality of life outcomes in trauma patients: a scoping review. *J Patient Rep Outcomes*. 2021 Aug 9;5(1):68. doi: 10.1186/s41687-021-00346-6.

Peer-reviewed books and book chapters

NA

Other publications including popular science books/presentations

1. **Gerdin Wärnberg M**, Berg J, Bhandarkar P, Chatterjee A, Chatterjee S, Chintamani C, Felländer-Tsai L, Gadgil A, Ghag G, Hasselberg M, Juillard C, Khajanchi M, Kizhakke Veetil D, Kumar V, Kundu D, Mishra A, Patil P, Roy N, Roy A, David S, Singh R, Solomon H, Soni KD, Strömmer L, Tandon M; Trauma life support training Effectiveness Research Network (TERN) collaborators. A pilot multicentre cluster randomised trial to compare the effect of trauma life support training programmes on patient and provider outcomes. BMJ Open. 2022 Apr 18;12(4):e057504. doi: 10.1136/bmjopen-2021-057504.

Number of publications

Total number of peer-reviewed original articles

42

Total number of peer-reviewed research review articles

2

Total number of other publications including patents

8

Number of peer-reviewed original articles from 2015–2023

34

Number of peer-reviewed research review articles from 2015–2023

2

Number of other publications including patents from 2015–2023

5

Letter of support

Letter of Support (English)

See following page for attachment

Department of Physiology and Pharmacology
Section of Anesthesiology and Intensive Care Medicine
Lars I Eriksson, MD, PhD, FRCA
Professor, Academic Chair

Letter of Support

Martin Gerdin Wärnberg is employed as a resident in Anesthesia and Intensive Care at Function Perioperative Medicine and Intensive Care, Karolinska University Hospital, Solna. His employment level is 100%. Working hours corresponding to 30% will be released for the research project in question.

Stockholm March 27nd 2023

Lars I Eriksson, MD, PhD, FRCA
Professor, Academic chair
Director of Research & Development, Education and Innovation
Function Perioperative Medicine and Intensive Care
Section for Anesthesiology and Intensive Care Medicine
Karolinska Institutet and Karolinska University Hospital

Adress
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CV

CV - Martin Gerdin Wärnberg

Project leader: Martin Gerdin Wärnberg
Birthdate: 19880127
Gender: Male
Country: Sweden
Doctoral degree: 2015-11-27
Academic title: Associate professor
Employer: Karolinska Institutet

Doctors degree

Examination	Organisation	Dissertation title (original language)	Supervisor
30302. Public Health, Global Health, Social Medicine and Epidemiology, 2015-11-27	Karolinska Institutet, PHS (Institutionen för folkhälsovetenskap)	The risk of dying: predicting trauma mortality in urban Indian hospitals	Johan von Schreeb

Educational history

Research education

Examination	Organisation	Dissertation title	Name of supervisor
PhD degree, 30302. Public Health, Global Health, Social Medicine and Epidemiology, 2015-11-27	Karolinska Institutet, Sweden, PHS (Institutionen för folkhälsovetenskap)	The risk of dying: predicting trauma mortality in urban Indian hospitals	Johan von Schreeb

Basic education

Year	Examination
2015	30299. Other Clinical Medicine, University medical Degree, doctor of medicine (MD), Karolinska Institutet, Sweden

Professional history

Employments

Period	Position	Part of research in employment	Employer
augusti 2020 - Present	ST-läkare, Permanent employment	0	Karolinska University Hospital, Sweden, Function Perioperative Medicine and Intensive Care
mars 2023 - Present	Principal Researcher, Permanent employment	85	Karolinska Institutet, Sweden, GPH (Institutionen för global folkhälsa)
maj 2018 - mars 2023	Postdoctoral fellow, Permanent employment	85	Karolinska Institutet, Sweden, GPH (Institutionen för global folkhälsa)
januari 2016 - maj 2018	Researcher, Project employment	50	Karolinska Institutet, Sweden, PHS (Institutionen för folkhälsovetenskap)
augusti 2015 - mars 2018	AT-läkare, Permanent employment	0	Karolinska University Hospital Huddinge, Sweden, Forskar-AT

Period	Position	Part of research in employment	Employer
maj 2012 - december 2015	PhD student	100	Karolinska Institutet, Sweden, PHS (Institutionen för folkhälsovetenskap)
juni 2014 - augusti 2015	Other	0	Karolinska University Hospital Huddinge, Sweden, Ortopedkliniken
februari 2012 - maj 2012	Research assistant	100	Karolinska Institutet, Sweden, PHS (Institutionen för folkhälsovetenskap)
september 2011 - januari 2012	Research assistant	75	Karolinska Institutet, Sweden, PHS (Institutionen för folkhälsovetenskap)
februari 2011 - augusti 2011	Research assistant	50	Karolinska Institutet, Sweden, PHS (Institutionen för folkhälsovetenskap)
augusti 2010 - januari 2011	Research assistant	25	Karolinska Institutet, Sweden, PHS (Institutionen för folkhälsovetenskap)

Post doctoral assignments

Period	Organisation	Subject
maj 2018 - mars 2023	Karolinska Institutet, Sweden, GPH (Institutionen för global folkhälsa)	30302. Public Health, Global Health, Social Medicine and Epidemiology

Research exchange assignments

Period	Type	Organisation	Subject
oktober 2016 - november 2016	Guest researcher	University of California, San Francisco, USA, Center for Global Surgical Studies	30299. Other Clinical Medicine
februari 2016 - april 2016	Guest researcher	Tata Institute of Social Sciences	30302. Public Health, Global Health, Social Medicine and Epidemiology
juli 2012 - november 2012	Guest researcher	Tata Institute of Social Sciences	30302. Public Health, Global Health, Social Medicine and Epidemiology

Interruptions in research

Period	Description
2020-08-10 - 2023-03-28	Ongoing specialisation in anaesthesia and intensive care.
2019-04-29 - 2020-04-19	Parental leave 85%
2018-09-03 - 2019-03-01	Parental leave 85%
2015-08-31 - 2018-03-04	Interruptions in research for a total of 12 months during this time period because of clinical rotations in internal medicine, surgery, psychiatry and primary care during AT.

Merits and awards

Docentur

Year	Subject	Organisation
2020	303. Health Sciences	Karolinska Institutet, Sweden

Supervised persons

Year	Supervised persons	University (supervisee)	Role
2027	PhD student, Jonatan Attergrim	Karolinska Institutet, Sweden, GPH (Institutionen för global folkhälsa)	Main supervisor
2024	PhD student, Johanna Berg	Karolinska Institutet, Sweden	Main supervisor
2022	PhD student, Siddarth David	Karolinska Institutet, Sweden, PHS (Institutionen för folkhälsovetenskap)	Main supervisor
2022	PhD student, Uzma Khan	Karolinska Institutet, Sweden	Main supervisor
2027	PhD student, Kelvin Szolnoky	Karolinska Institutet, Sweden, MEB (Institutionen för medicinsk epidemiologi och biostatistik)	Secondary supervisor
2020	PhD student, Lukas Berglund	Karolinska Institutet, Sweden, CLINTEC (Institutionen för klinisk vetenskap, intervention och teknik)	Secondary supervisor
2018	Student, Erika Bengtsson	Karolinska Institutet, Sweden, PHS (Institutionen för folkhälsovetenskap)	Main supervisor
2018	Student, Tobias Halldén	Karolinska Institutet, Sweden, PHS (Institutionen för folkhälsovetenskap)	Main supervisor
2017	Student, Adam Elfving	Örebro University, Sweden	Main supervisor
2017	Student, Anton Ahlbäck	Örebro University, Sweden	Main supervisor
2017	Student, Mike Mansourati	Karolinska Institutet, Sweden, PHS (Institutionen för folkhälsovetenskap)	Main supervisor
2017	Student, Ruut Seger	Karolinska Institutet, Sweden, PHS (Institutionen för folkhälsovetenskap)	Main supervisor
2016	Student, Alice Claeson	Karolinska Institutet, Sweden	Main supervisor
2016	Student, Jonatan Attergrim	Karolinska Institutet, Sweden	Main supervisor
2016	Student, Mattias Sterner	Karolinska Institutet, Sweden	Main supervisor

Research grants awarded in competition

Period	Funder	Project leader	Your role	Total amount (SEK)
2022 - 2023	Swedish Society of Medicine, Sweden - Other financing agencies and organisations	Martin Gerdin Wärnberg	Applicant	200 000
2022 - 2023	KI - Karolinska institutet, Sweden - Other financing agencies and organisations	Martin Gerdin Wärnberg	Applicant	122 100
2021 - 2022	Carnegiestiftelsen, Sweden - Oterh private actors	Martin Gerdin Wärnberg	Applicant	100 000
2021 - 2022	Laerdal Foundation or Acute Care Medicine, Not Sweden - International organisations, Norway	Martin Gerdin Wärnberg	Applicant	220 000

Period	Funder	Project leader	Your role	Total amount (SEK)
2020 - 2022	VR - The Swedish Research Council, Sweden - Other financing agencies and organisations	Martin Gerdin Wärnberg	Applicant	790 020
2018 - 2019	Sweden - Other governmental agencies,	Martin Gerdin Wärnberg	Applicant	976 000
2018 - 2019	KI - Karolinska institutet, Sweden - Other financing agencies and organisations	Martin Gerdin Wärnberg	Applicant	89 400
2017 - 2018	Sweden - Other governmental agencies,	Martin Gerdin Wärnberg	Applicant	976 000
2017 - 2020	VR - The Swedish Research Council, Sweden - Other financing agencies and organisations	Martin Gerdin	Applicant	4 000 000

Publications

Publications - Gerdin Wärnberg, Martin

Project leader: Martin Gerdin Wärnberg
Birthdate: 19880127
Gender: Male
Country: Sweden
Doctoral degree: 2015-11-27
Academic title: Associate professor
Employer: Karolinska Institutet

Register

Terms and conditions

The application shall be signed by the applicant and also by an authorised representative of the administrating organisation. The representative is normally the head of the department where the research will be carried out, but this is dependent on the administrating organisation's structure.

The *applicant's* signature confirms that

- the information in the application is correct and complies with the Swedish Research Council's instructions
- secondary occupations and commercial ties have been reported to the administrating organisation and that nothing has emerged that breaches good research practice
- the permits and approvals required have been obtained before the research is started, such as permits from the Swedish Medical Products Agency or approval from The Swedish Ethical Review Authority or an ethical committee on animal experiments
- the applicant will comply with all other conditions applicable to the grant.

The signature of the *administrating organisation* confirms that

- the research or research-supporting activities described can be given room at the administrating organisation during the period and to the extent stated in the application
- the applicant will be employed by the administrating organisation during the period covered by the application
- the administrating organisation approves of the budget in the application
- the administrating organisation will comply with all other conditions applicable to the grant.

The above points shall have been discussed by the parties before the representative of the administrating organisation approves and signs the application.