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)