Trial Steering Committee Charter

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

This document is based on the MRC CTU Template Trial Steering Committee Charter (version 1.02).

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Introduction

The purpose of this document is to outline the composition, terms of reference, duties, powers, decision-making processes and interactions of the Trial Steering Committee (TSC) for this trial. It will detail the scheduling of meetings, how information will be communicated to and from the TSC, the regularity and structure of meetings, and how the TSC will coordinate with other committees involved in the trial.

Trial 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 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

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 approach for informed consent for follow up once they are admitted or telephonically if they are transferred. In-hospital data collection from medical records 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 before final analysis of the data.

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

Special considerations

This trial is not yet fully funded. The TMG has decided to proceed with the trial with the expectation that funding will be secured. The TSC 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.

Roles and Responsibilities

The TSC's responsibility is to oversee the trial and offer guidance to the Trial Management Group (TMG) through its independent Chairman. The specific roles are:

- Providing expert supervision of the trial;
- Keeping all non-public trial information confidential;
- Deciding on the trial's future progression, based on recommendations from the Data Monitoring Committee (DMC) and the TMG;
- Evaluating regular trial reports from the TMG;
- Overseeing the completion of CRFs and advising on TMG's future strategies for satisfactory completion;
- Monitoring follow-up rates and assessing TMG's strategies to address any issues;
- Sanctioning any changes to the protocol when necessary;
- Approving TMG's proposals for alterations in the trial's design, including new substudies;
- Supervising the prompt disclosure of trial findings;
- Providing input on the policy for publication;
- Approving and giving feedback on the main trial manuscript.

Early in the trial

All prospective independent members of the Trial Steering Committee (TSC) should review the trial protocol prior to the start of participant enrollment. At that time, the trial will also have been evaluated by the Sponsor and Coordinator, examined by other trial committees, and assessed by a research ethics committee. Should a prospective independent TSC member have significant concerns about any aspect of the trial, such as the protocol, operational details, or ethical issues, they must communicate these concerns to the Trial Management Group. While TSC members are expected to offer critical oversight of the trial as it progresses, they should also be supportive of the trial's objectives and methodologies. TSC members will not be asked to formally sign a contract.

Composition

The majority of members of the TSC, including the Chair, should be independent of the trial. Non-independent members will also be part of the TSC. The Chair should have previous experience of serving on trial committees and experience of Chairing meetings, and should be able to facilitate and summarise discussions. There will be a facilitator who is a member of either the Sponsor or the Coordinator. The Facilitator will be responsible for arranging meetings of the TSC, coordinating reports, producing and circulating minutes and action points.

Relationships

The TSC will be responsible for overseeing the trial and will be accountable to the Sponsor and Coordinator. The TSC will receive reports from the TMG and DMC, and will provide advice to the TMG. The TSC will not be involved in the day-to-day running of the trial. No payments will be made to TSC members for their time.

Any competing interests, both real or potential, should be disclosed. These are not restricted to financial matters – involvement in other trials or intellectual investment could be relevant. Although members may well be able to act objectively despite such connections, complete disclosure enhances credibility.

Organisation of meetings

The TSC will meet virtually at least yearly. At the request of the TSC or TMG, interim meetings will be organised. Some trial issues will need to be dealt with by email between meetings. TSC members should be prepared for such instances. Effort will be made for all

members to attend. Presence will usually be limited to the TSC members, observers from the Sponsor and/or Coordinator and the Facilitator. Other attendees may be invited for all or part of the meeting by the TSC. The observers are not members of the TSC but may be invited to provide expert input; other observers will be at the discretion of the TSC and the Facilitator but may include members of the TMG other than the PI.

If an independent member does not attend a meeting or provide comments when requested between meetings, it should be ensured that the independent member is available for the next meeting. If an independent member does not attend the next meeting or provide comments when next requested, they should be asked if they wish to remain part of the TSC. If an independent member does not attend a third meeting, strong consideration should be given to replacing this member.

Trial documentation and procedures

A short report will be prepared by the trial team following a standard template. This report will include completion rates of CRF's, follow-up rates, and any other relevant information. The report will be circulated to the TSC at least 2 weeks prior to the meeting. The TSC will review the report and provide feedback to the TMG. The TSC will also receive reports from the DMC and will provide feedback to the TMG.

Decision making

After reviewing the relevant reports, possible decision from the TSC includes:

- No action required, the trial continues as planned;
- Approving or suggesting changes to the trial protocol;
- Stopping the trial early based on a recommendation from the DMC;

Every effort should be made to reach a consensus. If a consensus cannot be reached, a vote will be taken. The Chair will have the casting vote. The TSC will be able to make recommendations to the Sponsor and Coordinator.

The TSC is quorate if at least two of the independent members are present, including the chair, and the principal investigator.

Reporting

The TSC will report their decisions (via the Facilitator) to the TMG who will be responsible for implementing any actions resulting. The TSC may also provide feedback to the DMC and, where appropriate, to the Sponsor and/or Coordinator. Notes of key points and actions will be made by the Facilitator and circulated to the TSC within 1 week of the meeting. The TSC Chair will sign off the final version of minutes or notes.

The TSC is the oversight body for the trial. However, the TSC should have good reason before deciding not to accept requests from the TMG and recommendations from the DMC. If there are serious problems or concerns with the TSC decision following an DMC recommendation, a joint meeting of the TSC and DMC should be held. The information to be shown would depend upon the action proposed and each committees' concerns.

Depending on the reason for the disagreement confidential data and/or data by trial and may have to be revealed to all or some of those attending such a meeting: this would be minimised where possible. The meeting would be Chaired by an external expert who is not directly involved with the trial.

After the trial

The TSC will oversee the timely analysis, writing up and publication of the main trial results. The independent members of the TSC will have the opportunity to read and comment on the proposed main publications of trial data prior to submission and abstracts and presentations during the trial. This review may be concurrent to that of the trial investigators and DMC.

Amendments

This TSC charter can be amended as needed during the course of the study. All amendments will be documented with sequential version numbers and revision dates, and will be recorded in the TSC notes.