

ATLS® vs standard care trial

Trial Management Group meeting, 11th March 2024

Members present

- Martin Gerdin Wärnberg (chair) (MGW)
- Debojit Basak (DB)
- Abhinav Bassi (AB)
- Johanna Berg (JB)
- Karla Hemming (KH)
- Samriddhi Ranjan (SR)
- Li Felländer-Tsai (LFT)

Members excused

- Girish D Bakhshi (GB)
- Shamita Chatterjee (SC)
- Kapil Dev Soni (KDS)
- Vivekanand Jha (VJ)
- Monty Khajanchi (MK)
- Anurag Mishra (AM)
- Nobhojit Roy (NR)
- Rajdeep Singh (RS)
- Lovisa Strömmer (LS)

Agenda

1. Decide to go ahead with the attached protocol for ethics submissions
2. Decide to use the attached Trial Management Charter
3. Decide to join Trial Steering Committee and Data Monitoring Committee into a Joint Trial Steering and Data Monitoring Committee
4. Identify external members for the joint committee
5. Present cluster screening progress
6. Present timeline
7. Additional points for discussion

Notes and decisions

1. We decided to go ahead with the protocol for ethics submission
2. We decided to use the circulated Trial Management Charter
3. We decided to combine the Trial Steering Committee and Data Monitoring Committee into a Joint Trial Steering and Data Monitoring Committee. The protocol and trial committee charters will be updated to reflect this change.
4. We discussed the need for external members in the joint committee, including a chair person with previous experience of participating in and preferably chairing trial steering committees, a subject matter expert, a statistician and a patient or community representative. Suggestions should be sent to MGW.
5. Nine hospitals have undergone the initial screening process and six hospitals have undergone in-depth interviews. We will initiate the ethical review process in these hospitals and five of them will be included in the first batch. LFT asked what the screening process look like and MGW explained that there are three screening steps, first a brief online form that can either be filled in by prospective centres directly or through a short call. We then discuss all screened hospitals at a trial team or trial management group meeting and decide which centres we should invite for an in-depth screening interview.
6. MGW presented the timeline. We expect to register the trial in Clinical Trial Registry – India (CTRI) and ClinicalTrials.gov during March. We will submit for ethical review during April-June and apply for Health Ministry Screening Committee (HMSC) approval during the same time period. We hope to start data collection in the first batch of hospitals during October.
7. Additional discussion points:
 - a. KH asked if there are any plans to publish the protocol. We discussed that this should be a good time to publish the protocol, for example in Trials or BMJ Open.

Next steps

- Screen more sites
- Send suggestions for Joint Trial Steering and Data Monitoring Committee members to MGW
- Next meeting is on May 15