

ATLS® vs standard care trial

Trial Management Group meeting, 15th May 2024

Members present

- Martin Gerdin Wärnberg (chair) (MGW)
- Debojit Basak (DB)
- Samriddhi Ranjan (SR)
- Li Felländer-Tsai (LFT)
- Kapil Dev Soni (KDS)
- Monty Khajanchi (MK)
- Nobhojit Roy (NR)
- Rajdeep Singh (RS)
- Karla Hemming (KH)
- Vivekanand Jha (VJ)

Members excused

- Lovisa Strömmer (LS)
- Abhinav Bassi (AB)
- Johanna Berg (JB)
- Girish D Bakhshi (GB)
- Shamita Chatterjee (SC)
- Anurag Mishra (AM)

Additional representation from the trial team

- Prashant Kharat (PK)

Agenda

1. Update on ethics and regulatory applications
2. Discussion on measuring adherence to ATLS
3. Suggestion for Joint Steering and Data Monitoring Committee
4. Additional points

Notes and decisions

1. SR presented the progress with regards to ethics and regulatory applications. We are on track to start patient inclusion in October.
2. Adherence to ATLS training is a potential confounder, especially if we don't see a difference following the training, i.e. it can be claimed that physicians are already treating patients according to ATLS thanks to their baseline training and that's why we don't see an improvement. We discussed whether and how this can be measured. Options:
 - a. WHO trauma care checklist
 - b. ATLS proficiency evaluation score sheet?
 - c. Other published checklists

There was a consensus that ATLS adherence should be measured and that the WHO trauma care checklist would be the most straightforward way of doing that. We also said that we will check the checklist against the most recent ATLS guidelines to see if there are items that need to be added. KDS pointed out the GCS is assessment is highlighted in the ATLS guidelines and should be considered. We also discussed how to sample patients for assessment and decided to discuss this with Jessica Kasza at Monash University.
3. We discussed the composition of the Joint Steering and Data Monitoring Committee. The proposed members who will be asked to form this committee are:
 - a. Ganesan Karthikeyan (chair) - Clinical, interventional cardiologist and a Professor of Cardiology at All India Institute of Medical Sciences, New Delhi, India.
 - b. Richard Hooper - Professor of Medical Statistics at Queen Mary University of London, UK.
 - c. Kathryn Chu - Director and Professor, Centre for Global Surgery, Stellenbosch University, South Africa.
 - d. Vikram Kate, JIPMER, Puducherry
 - e. Patient representative, preferably someone who's representing a patient organization.

RS asked if there needs to be a legal representative, but this is not a formal requirement.
4. RS offered to help with approaching the centres in Chandigarh to help with issues related to the ethics application.