

ATLS® vs standard care trial

Trial Management Group meeting, 13th June 2024

Members present

- Martin Gerdin Wärnberg (chair) (MGW)
- Debojit Basak (DB)
- Samriddhi Ranjan (SR)
- Kapil Dev Soni (KDS)
- Monty Khajanchi (MK)
- Abhinav Bassi (AB)
- Johanna Berg (JB)

Members excused

- Lovisa Strömmer (LS)
- Girish D Bakhshi (GB)
- Shamita Chatterjee (SC)
- Anurag Mishra (AM)
- Li Felländer-Tsai (LFT)
- Nobhojit Roy (NR)
- Rajdeep Singh (RS)
- Karla Hemming (KH)
- Vivekanand Jha (VJ)

Agenda

1. Update on ethics and regulatory applications
2. Discussion on proposal to measure ATLS adherence, see amended protocol and checklist
3. Additional points

Notes and decisions

1. SR presented the progress with regards to ethics and regulatory applications. We have received ethics approval from one site and have received minor queries from the ethics committee in another site. The remaining applications will be reviewed in upcoming meetings. We aim to submit the HMSC application within the next two weeks.
2. We discussed how to measure adherence to ATLS principles, including the draft checklist for inclusion in the CRF. The consensus was:
 - a. To focus on the primary survey, because the secondary survey will be difficult to capture
 - b. To split the primary survey indicators into examinations that are indicated for all patients, and interventions that may be indicated depending on findings. Using this model, the adherence can be expressed as a proportion, which can be used to calculate the number of patients that need to be sampled for assessing this outcome. MK, JB and DB will revise the current draft based on this input.
 - c. We decided that the start of the primary outcome would be defined as the time when the physician first sees the patient. We also decided to tentatively consider examinations and interventions performed within the first hour after the start of the primary survey as part of this survey. We will also consider timestamping the included items.
3. There were no additional points.