



ADVANCE TRAUMA

Trial Management Group

Protocol

Meeting

August 27, 2025

Present

Members

Martin Gedin Wörnberg, Chair (MGW)
Vivekanand Jha (VJ)
Johanna Berg (JB)
Shamita Chatterjee (SC)
Prashant Kharat (PK)
Rajdeep Singh (RS)

Adjunct member

Arpita Ghosh (AG), Head Biostatistics and Data Science, The George Institute

Apologies

Members

Anurag Alok (AA)
Girish Bakshi (GB)
Debojit Basak (DB)
Abhinav Bassi (AB)
Kapil Dev Soni (KDS)
Karla Hemming (KH)
Monty Khajanchi (MK)
Anna Olofsson (AO)
Nobhojit Roy (NR)
Lovisa Strömmer (LS)
Li Felländer-Tsai (LFT)

Trial Management Group

Protocol

Meeting

August 27, 2025

§ 1 Agenda

- Batch 1 patient inclusion
- Batch 1 data review
- Batch 2 progress update
- Batch 3 progress update
- Protocol paper progress
- Any other business

§ 2 Approval of the agenda

The agenda was approved.

§ 3 Batch 1 patient inclusion

Patient inclusion is progressing largely according to plan (Table 1). The target of at least 12 participant per period per cluster is reached for a majority of periods and clusters. Two clusters had inclusion rates below the target attributable to a change of the clinical research coordinator collecting the data and misunderstandings regarding the eligibility criteria.

Table 1. Number of enrolled participants per cluster per period (month). Bold indicates that the target of at least 12 participants was met.

	March	April	May	June	July	August*
Cooper, Mumbai	13	11	10	5	5	9
HIMS, Dehradun	20	27	29	26	21	18
SSKM, Kolkata	47	66	58	48	59	22
GMC, Chandigarh	4	12	33	32	12	8
CMC, Ludhiana	12	3	3	18	12	6

*Final numbers for August are not yet in.

§ 4 Batch 1 data review

We reviewed selected data from batch 1 (Table 2). There is a striking difference in the number of injuries recorded across sites. The injury recording is reviewed continuously and is improving overall, but it was initially difficult to get all injuries recorded as separate instances instead of only the main injury. For example, participant injuries would be recorded as simply “Head injury” instead of “Subdural hematoma”, “Multiple rib fractures” and “Haemothorax”. This has improved through weekly individual reviews.

RS raised the point that the difference in the number of injuries could be because SSKM is a referral center receiving mostly severely injured patients, which definitely can contribute to the discrepancy. SSKM also has a more experienced data collection team. JB asked if the clinical research coordinators receive any training in injury recording. MGW said that we refer them to the WHO online module on ICD-coding and PK said that DB has developed an injury recording

Trial Management Group

Protocol

Meeting

August 27, 2025

guideline and has discussed the injury coding with the clinical research coordinators. JB suggested that we could identify an additional online resource to help with this.

We discussed that no transfers were recorded. It turned out that this was because it was interpreted as patients who were transferred out from the participating centres rather than those transferred in. This will be corrected. We also noticed that the median GCS at HIMS was very low compared to the other clusters, and that there was a discrepancy between the low GCS and the mortality, which was also low. PK explained that this is because the clinical research coordinator at HIMS misinterpreted another score as the GCS, but that this has been corrected and that the data is being updated.

We further discussed how to improve the data review by adding the full range to continuous variables.

Table 2. Participant characteristics March-August 2025.

	Cooper (n = 45)	HIMS (n = 97)	SSKM (n = 315)	CMC (n = 48)	GMC (n = 60)	Overall (n = 565)
Total Injuries	107	259	1324	82	55	1827
Age in years, median (IQR)	36 (24-49)	34 (25-53)	39 (26-55)	32.5 (24-40)	40 (28-50)	36
Missing no.	1	3	0	0	2	6
Female sex, no. (%)	4 (9)	16 (17)	54 (17)	11 (23)	5 (9)	40 (16)
Missing no.	1	3	0	0	2	6
Mechanism of injury, no. (%)						
Transport	23 (51)	64 (66)	202 (64)	37 (77)	31 (52)	357 (63)
Fall	13 (29)	23 (24)	86 (27)	1 (02)	6 (10)	129 (23)
Assault	8 (17)	4 (4)	09 (3)	6 (13)	13 (22)	40 (07)
Self-harm	NA	2 (2)	NA	1 (2)	NA	3 (1)
Other	NA	1 (1)	18 (6)	3 (6)	2 (3)	24 (4)
Missing	1 (2)	3 (3)	NA	NA	8 (13)	12 (2)
Transfer, no. (%)	NA	NA	NA	NA	NA	NA
SBP, median (IQR)*	110 (100- 118)	120 (110- 140)	124 (113-135)	120 (100- 140)	120 (100- 140)	119
Missing, no.	4 (9)	4 (4)	20 (6)	3 (6)	8 (13)	39 (7)
RR, median (IQR)*	22 (19-24)	20 (18- 20)	20 (18-21)	20 (20- 23)	22 (20-22)	20
Missing, no. (%)	4 (9)	4 (4)	39 (12)	13 (27)	10 (17)	70 (12)
SpO2, median (IQR)*	98 (95-99)	98 (96- 98)	99 (97-100)	98 (97- 100)	97 (94-98)	98
Missing, no. (%)	4 (9)	4 (4)	10 (3)	1 (2)	10 (17)	29 (5)
GCS, median (IQR)*	13 (10-15)	8 (3-15)	15 (15-15)	15 (15-15)	15 (15-15)	13.2
Missing, no. (%)	10 (22)	4 (3)	17 (5)	2 (4)	10 (16)	43 (7)
CT, no. (%)	60	581	499	83	97	1320
Surgery, no. (%)	3 (7)	36 (37)	236 (74)	19 (40)	32 (53)	326
ICU admission, no (%)	36 (80)	12 (12)	122 (39)	7 (15)	4 (7)	181 (32)
Hospital disposition, no. (%)						

Trial Management Group

Protocol

Meeting

August 27, 2025

	Cooper (n = 45)	HIMS (n = 97)	SSKM (n = 315)	CMC (n = 48)	GMC (n = 60)	Overall (n = 565)
Alive	32 (71)	94 (97)	235 (75)	46 (96)	46 (77)	453 (80)
Dead	9 (20)	3 (3)	58 (18)	2 (4)	1 (2)	73 (13)
Transfer	NA	NA	2 (1)	NA	NA	2 (0)
Missing	4 (08.89)	NA	20 (6)	0	13	37

§ 5 Batch 2 progress update

We discussed the status at each site planned to participate in batch 2:

- Holy Family Hospital, Delhi: Clinical trial agreement signed and ethics approval received. Clinical research coordinator recruitment ongoing.
- Lokmanya Tilak Hospital, Mumbai: Clinical trial agreement signed, ethics application reviewed and queries replied to. Awaiting final ethics approval. Clinical research coordinator recruitment ongoing.
- King Edward Memorial Hospital, Mumbai: Awaiting final approval of clinical trial agreement and ethics. Clinical research coordinator recruitment ongoing.
- Dayanand Medical College, Ludhiana: Awaiting final signature on clinical trial agreement. Ethics application reviewed and queries replied to. Awaiting final ethics approval. Clinical research coordinator recruitment ongoing.
- Assam Medical College, Dibrugarh: Review of clinical trial agreement is ongoing. Ethics meeting is scheduled for September 25th, but we are working towards an earlier review. Clinical research coordinator recruitment ongoing.

The second batch is planned to start in September 2025. The start might be delayed because of the late review at Assam Medical College, but we are working towards solving that.

§ 6 Batch 3 progress update

We have received additional funding that should allow us to start batch 3. We have initiated the ethics process at one prospective site, Srinagar Government Medical College, and are screening additional sites. Kolkata Medical College has expressed interest and a full screening interview will be scheduled. Additional potential sites are:

- PGI Chandigarh: VJ has identified a contact person there and we are awaiting their response.
- Kalpana Chawla Government Medical College & Hospital: Has expressed interest previously and will be contacted.
- Pandit Bhagwat Dayal Sharma Post Graduate Institute of Medical Sciences: Has expressed interest previously and will be contacted.
- Rajawadi Hospital, Mumbai: The intended principal investigator moved to another hospital but MK will check if there is someone new there who might be interested.
- St. John's Medical College Hospital: They have participated in a previous project but had few patients with severe trauma.

Trial Management Group

Protocol

Meeting

August 27, 2025

- Indira Gandhi Institute of Medical Science, Patna: We have attempted to identify a contact person there but so far no one has been identified.

§ 7 Protocol paper update

Submitted to Trials, awaiting first editorial decision. A follow up email has been sent.

§ 8 Any other business

JB raised the point of retrospective data collection to reach the target of at least 12 participants per month. We are however meeting the target for most clusters and periods and we do not have ethics for retrospective inclusion as it is now.

SC raised the point that the ASA score is not recorded for most emergency cases in their centre. We will have to accept that this will be missing.

§ 9 Next meeting

October 6, 2025.