



ADVANCE TRAUMA

Trial Management Group

Protocol

Meeting

October 6, 2025

Present

Members

Martin Gedin Wärnberg, Chair (MGW)
Shamita Chatterjee (SC)
Prashant Kharat (PK)
Rajdeep Singh (RS)
Anurag Alok (AA)
Debojit Basak (DB)
Monty Khajanchi (MK)
Li Felländer-Tsai (LFT)

Adjunct member

Apologies

Members

Vivekanand Jha (VJ)
Johanna Berg (JB)
Girish Bakshi (GB)
Abhinav Bassi (AB)
Kapil Dev Soni (KDS)
Karla Hemming (KH)
Anna Olofsson (AO)
Nobhojit Roy (NR)
Lovisa Strömmér (LS)

Trial Management Group

Protocol

Meeting

October 6, 2025

§ 1 Agenda

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

§ 2 Batch 1 patient inclusion

We discussed the latest patient inclusion data (Table 1). Cooper Mumbai is again having surprisingly low inclusion numbers and additional reviews of the records at that site is planned. The numbers are surprising considering that we are including patients all days of the week from that site. In previous discussions with the site one reason for the low inclusions is that many patients come to the emergency department more than 48 hours after the injury, making them ineligible.

We discussed what we can learn from the first batch so far for the second batch in terms of patient inclusion: 1) doing everything that we can to keep the same CRC across the study period, 2) having a more in-depth training of the CRCs with records to screening emergency department records, and 3) monitor the inclusion process more closely during the initial months.

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	September	Total
Cooper, Mumbai	13	11	10	05	06	12	08	65
HIMS, Dehradun	20	27	29	26	21	28	12	163
SSKM, Kolkata	47	66	58	48	59	50	46	374
GMC, Chandigarh	04	12	33	32	30	21	39	171
CMC, Ludhiana	12	03	03	18	12	12	12	72

§ 3 Batch 1 data review

We discussed the data from the first batch so far (Table 2). We have not received updated online data from GMC because of an issue with the device used for uploading. This is concerning and we talked about how we need to enforce the availability of a device for this purpose for the CRC in our screening discussions with the sites. For this specific sites we also need to ensure that the device that now has been purchased is provided to the CRC. Data is however being collected on the paper CRFs, but not uploaded because of the device issue. Other issues that were discussed in the last meeting are now improving, the transfer data has been corrected and the error with the recording of GCS at HIMS is slowly improving. We also talked about the large impact of individual sites with high volumes and whether we should have a maximum number of patients that each site

Trial Management Group

Protocol

Meeting

October 6, 2025

can include. MK suggested that limit the number of shifts when we collect data in these very big sites. MGW said that accounting for the site volume when randomise sites to implementation sequences is another way that we are attempting to adjust for the impact of these large sites. Additional discussions with the biostatistics team are needed.

Table 2. Participant characteristics March-August 2025.

	Cooper (n = 62)	HIMS (n = 103)	SSKM (n = 390)	CMC (n = 57)	GMC (n = 60)	Overall (n = 565)
Total Injuries	126	311	1552	93	55	2086
Age in years, median (IQR)	36 (24-47)	34.5 (26-54)	37.5 (26- 54)	34 (25-42)	40 (28-51)	36.4
Missing no.	1	3	0	0	2	6
Female sex, no. (%)	5 (8)	19 (19)	70 (18)	12 (21)	5 (9)	111 (17)
Missing no.	1	3	0	0	2	6
Mechanism of injury, no. (%)						
Transport	35 (57)	66 (64)	249 (64)	37 (65)	31 (52)	418 (62)
Fall	18 (29)	28 (27)	106 (27)	06 (11)	06 (10)	164 (24)
Assault	09 (15)	4 (4)	10 (3)	08 (14)	13 (22)	44 (7)
Self-harm	NA	3 (3)	1 (0)	1 (2)	NA	5 (1)
Other	NA	2 (2)	24 (6)	5 (9)	2 (3)	33 (5)
Missing	NA	NA	NA	NA	8 (13)	8 (1)
Transfer, no. (%)	10 (16)	31 (30)	282 (72)	6 (11)	37 (61)	366 (54)
SBP, median (IQR)*	110 (100-118)	120 (110-140)	127 (114-136)	120 (110-140)	119.5 (100-140)	120
Missing, no.	4 (6)	5 (5)	23 (6)	4 (7)	8 (13)	44 (7)
RR, median (IQR)*	22 (20-24)	19 (18-20)	21 (18-21)	21 (20- 22.5)	22 (20-22)	20
Missing, no. (%)	4 (6)	5 (5)	45 (11)	13 (23)	10 (17)	77 (11)
SpO2, median (IQR)*	98 (97.25-98)	98 (96-98)	99 (97-100)	98 (97-100)	97 (94-98)	98
Missing, no. (%)	4 (6)	5 (5)	12 (3)	1 (2)	10 (17)	32
GCS, median (IQR)*	13 (10-15)	9 (8-15)	15 (15-15)	15 (15-15)	15 (15-15)	13
Missing, no. (%)	10 (16)	03 (3)	7 (2)	2 (4)	10 (17)	32 (5)
CT, no. (%)	38 (61)	161 (156)	351 (90)	46 (81)	42	638
Surgery, no. (%)	5 (8)	32 (31)	198 (51)	16 (28)	28 (53)	326
ICU admission, no (%)	38 (61)	12 (12)	150 (38)	11 (19)	4 (5)	181 (27)
Hospital disposition, no. (%)						
Alive	48 (77)	95 (92)	264 (68)	54 (95)	46 (77)	507 (75)
Dead	10 (16)	5 (5)	71 (18)	3 (5)	1 (2)	90 (13)
Transfer	NA	NA	2 (1)	NA	NA	2 (0)
Missing	4 (6)	3 (3)	53 (14)	0	13	73 (11)

§ 4 Batch 2 progress update

Trial Management Group

Protocol

Meeting

October 6, 2025

We are waiting for final approval from Assam Medical College and then we can start the second batch. Hopefully this approval comes soon so that we can start late October, which would mean that we are almost on time.

§ 5 Batch 3 progress update

We are in the process of screening sites for the third batch. Two more sites as backup are needed. We have had screening interviews with PGI Chandigarh and Kalpana Chawla Government Medical College & Hospital. PGI Chandigarh is a very large site and the decision today was that we need additional assurances from a senior member of the department, preferably the head, that they will be able to make adjustments to the resident rota to accommodate the study design. In Pandit Bhagwat Dayal Sharma Post Graduate Institute of Medical Sciences more than 50% of residents are already ATLS trained and they can therefore not be a site. We are working towards ethics submission at Kalkpani Chawla and SMHS Hospital, Government Medical College, Srinagar and we are scheduling a screening interview with Kolkata Medical College.

§ 6 Protocol paper update

The protocol paper is under review with Trials.

§ 7 Next meeting

The next meeting is on December 15, 2025.

§ 8 Any other business

No additional points were discussed.