

ADVANCE TRAUMA

Trial Management Group Meeting, May 21, 2025

Members Present

- Martin Gerdin Wärnberg (chair) (MGW)
- Debojit Basak (DB)
- Prashant Kharat (PK)
- Samriddhi Ranjan (SR)
- Rajdeep Singh (RS)
- Anurag Mishra (AM)

Members Excused

- Johanna Berg (JB)
- Vivekanand Jha (VJ)
- Monty Khajanchi (MK)
- Li Felländer-Tsai (LFT)
- Kapil Dev Soni (KDS)
- Shamita Chatterjee (SC)
- Nobhojit Roy (NR)
- Anna Olofsson (AO)
- Karla Hemming (KH)
- Abhinav Bassi (AB)
- Lovisa Strömmer (LS)
- Girish D Bakhshi (GB)

Agenda

1. **Batch 1 updates**

- Patient inclusions
- Summary data (see last page)
- ATLS training
- Nested staircase design and collection of secondary outcomes

2. Batch 2 updates

- Sites
 - Sion Hospital, Mumbai
 - KEM Hospital, Mumbai
 - Holy Family Hospital, Delhi
 - Dayanand Medical College, Ludhiana
 - Assam Medical College, Dibrugar

3. Batch 3 updates

- SMHS Hospital, Government Medical College, Srinagar
- PGIMS, Rohtak?
- PGIMER, Chandigarh?

4. Additional points

Notes and Decisions

1. Batch 1 updates

- Patient inclusions: There are two sites with lower than expected inclusion rates. For CMC Ludhiana, there was a misunderstanding about the inclusion during the nested staircase months, and then it has been very few presentations in May so far. For GMC Chandigarh, there was a delay in getting a CRC recruited, but that person is now including patients.
- The summary data reflects the current inclusion rates. Of note is that the number of injuries recorded is much higher in SSKM than the other sites. We have therefore arranged a couple of extra training sessions on how to record and code injuries.
- The first ATLS training happens in July and the arrangements are on track.
- We have seen very low inclusion rates during the randomised shifts during the first staircase months. One potential reason is that the shift timings are substantially shorter than the duration of the postings of the residents. We discussed expanding the randomised shifts to 12 hours, and having morning and night shifts. An additional suggestion would be to include all patients presenting during the days of the shifts for the quality of life and disability assessments, even if the adherence data cannot be collected for all these patients. This requires additional discussion.

2. **Batch 2 updates** We have obtained ethical approval from Holy Family Hospital in Delhi. We are in the process of obtaining ethical approvals and completing clinical trial agreements with the other sites.
3. **Batch 3 updates** We decided to schedule a screening interview with SMHS Hospital, Srinagar. The residents at PGIMS, Rohtak are already trained in ATLS. For PGIMER Chandigarh we need a new contact.
4. There were no additional points.

26 Feb – 21 May

Variables	Site 1 (n = 34)	Site 2 (n = 43)	Site 3 (n = 146)	Site 4 (n = 17)	Site 5 (n = 16)	Overall (n = 256)
Total Injuries	50	48	568	18	NA	684
Age in years, median (IQR)	M=36 (24-43)	M= 34 (26-58.5)	M= 40 (27.25-56)	M= 37 (32-41)	M= 55 (30.25-56.25)	40.4
Female sex, no. (%)	(3 Missing) 2 (5.88 %)	(1 Missing) 6 (13.95 %)	28 (19.18 %)	3 (17.65 %)	1 (6.25%)	40 (15.63%)
Mechanism of injury, no. (%)	6 Missing	1 Missing	NA	NA	14 Missing	21 Missing
Transport	9 (26.47)	25 (58.14%)	99 (67.81%)	13 (76.47%)	1 (50%)	147 (57.42%)
Fall	12 (35.29%)	15 (34.88%)	36 (24.66%)	2 (11.76%)	NA	65 (25.39%)
Assault	07 (20.59%)	01 (02.33%)	04 (02.74%)	2 (11.76%)	1 (50%)	15 (05.86%)
Self-harm	NA	NA	01 (0.68%)	NA	NA	1 (0.39%)
Other	NA	01 (02.33%)	NA	NA	NA	1 (0.39%)
Transfer, no. (%)	NA	NA	NA	NA	NA	NA
SBP, median (IQR)*	M=110 (94.5-110)	M=130 (110-140)	M= 127 (118-136)	M= 125 (120-140)	NA	126
Missing, no. (%)	6 (17.65%)	NA	8 (05.48%)	1 (05.88%)	16 (100%)	31 (12.11%)
RR, median (IQR)*	M=24 (18.75-24)	M= 19 (18-20)	M=19 (18-21)	M=20 (20-26)	NA	19.5
Missing, no. (%)	6 (17.65%)	NA	21 (14.38%)	8 (47.06%)	16 (100%)	51 (19.92%)
SpO2, median (IQR)*	M=98 (95.75-99)	M= 97 (96-98)	M = 99 (97-100)	M= 98 (97.75-99.25)	NA	98
Missing, no. (%)	6 (17.65%)	NA	5 (04.11%)	1 (05.88%)	16(100%)	02.46%
GCS, median (IQR)*	M= 13 (10-15)	M= 3 (3-5)	M= 15 (15-15)	M= 15 (15-15)	NA	11.5
Missing, no. (%)	13 (38.24%)	NA	3 (02.05%)	1 (05.88%)	NA	17 (06.64%)
CT, no. (%)	79	187	311	57	NA	634
Surgery, no. (%)	2 (05.88%)	16 (37.20%)	53 (36.30%)	9 (59.94)	NA	80
ICU admission, no. (%)	28 (82.35%)	2 (04.65%)	58 (39.72%)	2 (11.76%)	NA	90 (35.15%)
Hospital disposition, no. (%)	6 Not recorded (17.64%)	5 Not recorded (11.62%)	48 Not recorded (32.87%)	NA	NA	59 (23.04%)
Alive	20 (58.82%)	38 (88.37%)	75 (51.36%)	16 (94.11%)	NA	149 (58.20%)
Dead	08 (23.52%)	NA	23 (15.75%)	1(05.88%)	NA	32 (12.50%)
Transfer	NA	NA	NA	NA	NA	NA

*First measured in the emergency department. Abbreviations: CT Computed tomography, GCS Glasgow coma scale, ICU Intensive care unit, RR Respiratory rate, SBP Systolic blood pressure, SpO2 Blood oxygen saturation.