Figure 1. Participant Flow.

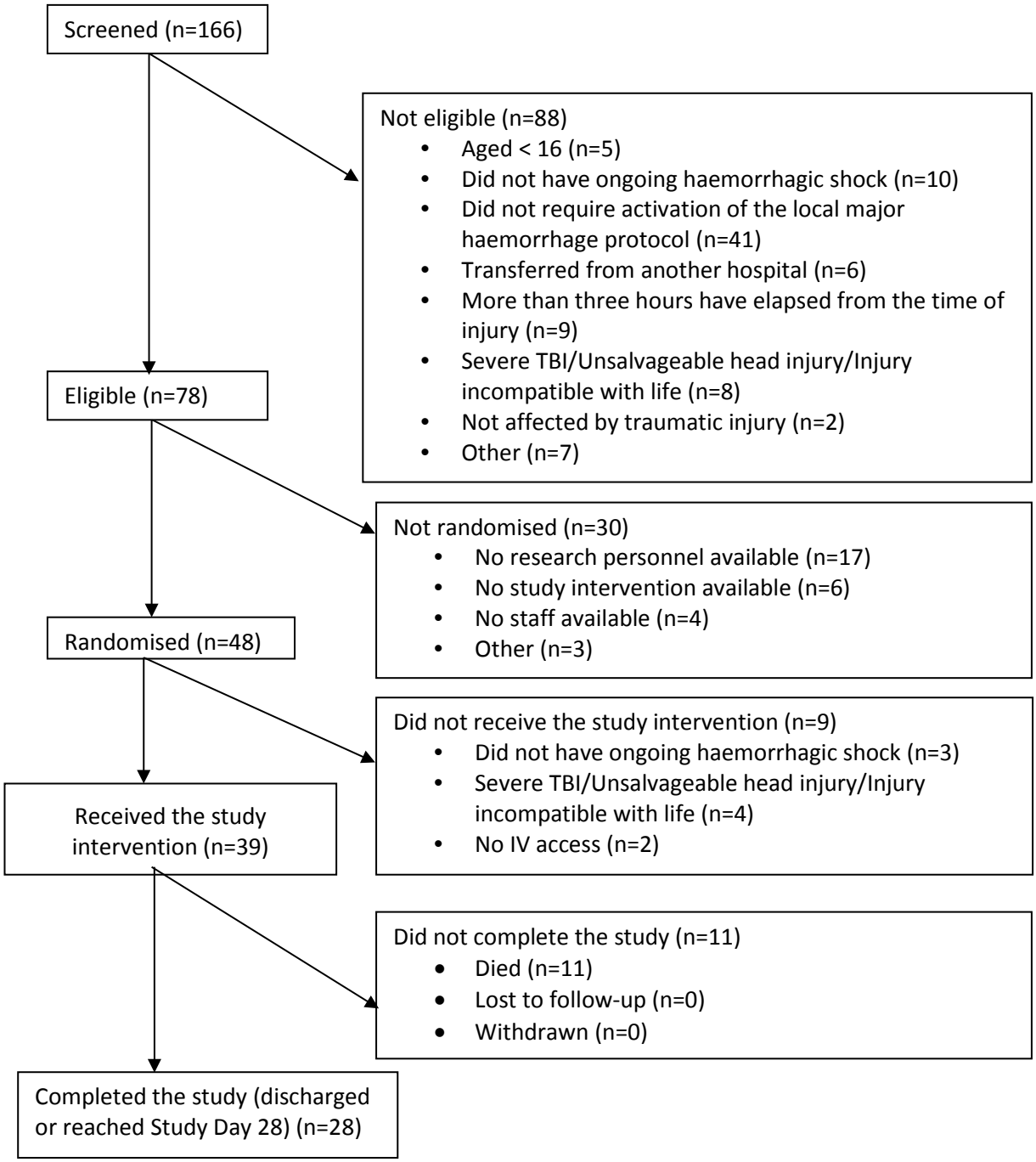

Table 1. Baseline characteristics.

	FIBRINOGEN CONCENTRATE ARM	PLACEBO ARM
SUBJECTS		
N	24	24
Age	38 (31 – 47)	36 (22 – 56)
Male	20 (83)	19 (79)
TIMELINES		
Injury to hospital[1] (min)	98 (77 – 118)	87 (66 – 116)
INJURIES & ADMISSION PHYSIOLOGY		
Blunt	21 (88)	18 (75)
ISS	34 (24 – 43)	29 (22 – 34)
Systolic blood pressure (mmHg)	86 (72 – 124)	95 (82 – 128)
Heart rate (min^{-1})	101 (88 – 116)	112 (93 – 126)
GCS	3 (3 – 14)	3 (3 – 15)
Clauss Fibrinogen (g/L)	1.9 (0.9 – 2.2)	2.3 (1.6-2.5)
EXTEM CA5	26 (15 – 28)	35 (26 – 42)
FIBTEM CA5	4 (3 – 7)	7 (4 – 12)
PRE RANDOMISATION		
TXA administered pre-admission	18 (75)	20 (83)
RBC (units)	1 (0-2)	1 (0-2)
FFP (units)	0 (0-1)	0 (0-2)
Crystalloid (mL)	0 (0 – 475)	0 (0 – 625)

Key: CA5 – clot amplitude at 5 minutes; FFP – fresh frozen plasma; GCS – Glasgow Coma Score; ISS – injury severity score; RBC – red blood cell; TXA – tranexamic acid

Data are number (%) for categorical variables and median (IQR) for continuous variables.

[1] One participant was admitted to hospital>3 hours after injury (subsequently defined as a protocol deviation)

Table 2. Fibrinogen levels over time by treatment arm.

Outcome	FIBRINOGEN CONCENTRATE ARM (n=24)	PLACEBO ARM (n=24)	Overall (n=48)	P-value
Mean (SD) Fibrinogen				
At admission	1.6 (0.7)	2.1 (0.9)	1.9 (0.8)	n/a
At 2 hours from admission during first active haemorrhage[1]	2.8 (1.3)	1.8 (0.6)	2.3 (1.1)	<0.0001
7 days from admission	6.7 (1.8)	7.5 (1.9)	7.1 (1.9)	0.2843

[1] P-value adjusted for value at admission

Table 3. Transfusion requirements during the first 24 hours.

	FIBRINOGEN CONCENTRATE ARM (n=24)	PLACEBO ARM (n=24)	P value
UNITS AT 3 HOURS			
RBC	4 (2 – 6)	2 (2 – 6)	0.73
FFP	3 (2 – 6)	3 (0 – 7)	0.92
Platelets	0 (0 - 1)	0 (0 - 1)	0.98
Cryoprecipitate	0 (0 - 2)	0 (0 – 1)	0.46
UNITS AT 6 HOURS			
RBC	3 (2 – 6)	2 (2 – 5)	0.62
FFP	4 (2 – 6)	3 (0 – 7)	0.77
Platelets	0 (0 – 1)	0 (0 – 1)	0.85
Cryoprecipitate	0 (0 – 2)	0 (0 – 0)	0.12
UNITS AT 24 HOURS			
RBC	4 (2 – 8)	2 (2 – 5)	0.38
FFP	5 (2 – 8)	3 (0 – 6)	0.39
Platelets	1 (0 – 1)	0 (0 – 1)	0.59
Cryoprecipitate	2 (0 – 2)	0 (0 – 0)	0.06

Key: FFP – fresh frozen plasma; RBC – red blood cell
Data are median IQR

Table 4. Serious adverse events.

	FIBRINOGEN CONCENTRATE ARM	PLACEBO ARM
SUBJECTS		
Number of participants in receipt of the study intervention	20	19
Number of participants experiencing at least one SAE[1]	13	11
Number of SAEs	29	21
Symptomatic thrombotic events	3	2
Arterial		
MI	0	0
Stroke	1	1
Other (arterial thrombus)	0	1
Venous		
DVT	0	0
PE	2	0
Sepsis	4	6
Organ Failure	10	2
Multiple organ failure	4	1
Single organ failure	6	1
New onset major bleeding	1	3
Uncontrolled major bleeding[2]	2	1
Other SAEs	9	7
Death		
All deaths[3]	8	3
Death due to bleeding	2 (25%)	1 (33%)

Key: DVT – deep venous thrombosis; MI – myocardial infarction; PE – pulmonary embolus; SAE – serious adverse event

Safety data were only collected for the 39 participants who were administered the study intervention.

[1] 11 participants experienced more than one SAE

[2] Major bleeding that was not controlled at any time from admission

[3] Includes all cases of multi organ failure, all cases of uncontrolled bleeding, one case of single organ failure in the active treatment arm and two other SAEs (one in the active treatment arm and one in the placebo arm).