Clinical trial results:
Pharmacokinetics of intramuscular tranexamic acid in trauma patients: a clinical trial

Summary

EudraCT number	2019-000898-23
Trial protocol	GB
Global end of trial date	12 February 2020

Results information

Result version number	v1 (current)
This version publication date	14 January 2021
First version publication date	14 January 2021
Summary attachment (see zip file)	Trauma-INTACT publication (Trauma-INTACT_British Journal of Anaesthesia (Trauma-INTACT publication).pdf) Trauma-INTACT figures (Trauma-INTACT_British Journal of Anaesthesia (Trauma-INTACT figures).ppt) Trauma-INTACT supplementary table (Trauma-INTACT_British Journal of Anaesthesia (Trauma-INTACT supplementary table).docx)

Trial information

Trial identification

Sponsor protocol code	2019/KEP/218

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03875937
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	London School of Hygiene and Tropical Medicine
Sponsor organisation address	Keppel Street, London, United Kingdom, WC1E 7HT
Public contact	Clinical Trials Unit, London School of Hygiene and Tropical Medicine, 0207 2994684, traumaim@Lshtm.ac.uk
Scientific contact	Clinical Trials Unit, London School of Hygiene and Tropical Medicine, 0207 2994684, traumaim@Lshtm.ac.uk

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	30 September 2020
Is this the analysis of the primary completion data?	Yes
Primary completion date	12 February 2020
Global end of trial reached?	Yes
Global end of trial date	12 February 2020
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

In an emergency situation, tranexamic acid is commonly administered intravenously, but this route might not always be feasible. If tranexamic acid injected intramuscularly is absorbed quickly, this route of administration of tranexamic acid might be an alternative to the intravenous route. We will determine how fast tranexamic acid is absorbed after intramuscular administration in bleeding trauma patients.

Protection of trial subjects:

The trial was done in accordance with the good clinical practice guidelines by the International Conference on Harmonisation. The procedure at each site was approved by the relevant ethics committee and regulatory agencies. Consent was obtained from participants if their physical and mental capacity allowed (as judged by the treating clinician). If a participant was unable to give consent, proxy consent was obtained from a relative or representative. If a proxy was unavailable, then consent was waived. When consent was waived or given by a proxy, the participant was informed about the trial as soon as possible, and consent was obtained for ongoing data collection, if needed.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	17 September 2019
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	United Kingdom: 30
Worldwide total number of subjects	30
EEA total number of subjects	30

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	1

Adults (18-64 years)	20
From 65 to 84 years	6
85 years and over	3

Subject disposition

Recruitment

Recruitment details:

The Trauma-INTACT trial enrolled 31 bleeding trauma patients aged 16 and older in 2 hospitals in the UK (1 patient was withdrawn before trial treatment was given so is not included in the analysis).
The first patient was randomised on 17/09/19 and the final patient on 07/02/20.

Pre-assignment

Screening details:

All adult (appear to be at least 16 years old) bleeding trauma patients, who have received 1 gram of intravenous tranexamic acid (TXA) and for whom a second dose of TXA is clinically indicated.

Period 1

Period 1 title	Overall trial (overall period)
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Arm title	Tranexamic acid

Arm description: -

Arm type	Experimental
Investigational medicinal product name	Tranexamic Acid
Investigational medicinal product code	B02AA02
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Patients received two 5mL (0.5g each) intramuscular injections of tranexamic acid.
(All patients had already received a loading dose of 1g IV tranexamic acid, as per clinical guidelines, before being enrolled in the trial)

Number of subjects in period 1	Tranexamic acid
Started	30
Completed	30

Baseline characteristics

Reporting groups	
Reporting group title	Overall trial (overall period)

Reporting group description: -

Reporting group values	Overall trial (overall period)	Total	
Number of subjects	30	30	
Age categorical Units: Subjects			
Adolescents (12-17 years)	1	1	
Adults (18-64 years)	20	20	
From 65-84 years	6	6	
85 years and over	3	3	
Gender categorical Units: Subjects			
Female	4	4	
Male	26	26	

End points

End points reporting groups

Reporting group title	Tranexamic acid

Reporting group description: -

Primary: Serum concentration over time

End point title	Serum concentration over time[1]

End point description:

End point type	Primary

End point timeframe:

Within 4 minutes of administration of i.m. TXA

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: See publication attached

End point values	Tranexamic acid			
Subject group type	Reporting group			
Number of subjects analysed	30			
Units: mg L-1	5			

Attachments (see zip file)	Trauma-INTACT figures/Trauma-INTACT_British Journal of

Statistical analyses

No statistical analyses for this end point

Primary: Serum concentration over time

End point title	Serum concentration over time[2]

End point description:

End point type	Primary

End point timeframe:

Within 11 minutes of i.m. TXA

Notes:

[2] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: See publication attached

End point values	Tranexamic acid			
Subject group type	Reporting group			
Number of subjects analysed	30			
Units: mg L-1	10			

Attachments (see zip file)	Trauma-INTACT figures/Trauma-INTACT_British Journal of

Statistical analyses

No statistical analyses for this end point

Secondary: Local reactions at injection site

End point title	Local reactions at injection site

End point description:

End point type	Secondary

End point timeframe:

Up to 7 days

End point values	Tranexamic acid			
Subject group type	Reporting group			
Number of subjects analysed	30			
Units: N/A				
Erythema	2			
Induration and subcutaneous nodules	4			
Bruising	8			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events: Up to 7 days	
Assessment type	Systematic
Dictionary used	
Dictionary name	MedDRA
Dictionary version	22.0
Reporting groups	
Reporting group title	Tranexamic acid

Reporting group description: -

Serious adverse events	Tranexamic acid		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 30 (0.00%)		
number of deaths (all causes)	9		
number of deaths resulting from adverse events	0		

Frequency threshold for reporting non-serious adverse events: 5 %

Non-serious adverse events	Tranexamic acid		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	1 / 30 (3.33%)		
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	1 / 30 (3.33%)		
occurrences (all)	1		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported