



Clinical trial results:

STOP-MSU – Stopping haemorrhage with Tranexamic acid for hyperacute Onset Presentation including Mobile Stroke Units

Summary

EudraCT number	2020-004746-10
Trial protocol	FI
Global end of trial date	28 May 2023

Results information

Result version number	v1 (current)
This version publication date	18 May 2024
First version publication date	18 May 2024

Trial information

Trial identification

Sponsor protocol code	NTA1702
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03385928
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	The Florey Institute of Neuroscience and Mental Health
Sponsor organisation address	245 Burgundy Street, Heidelberg, Australia, VIC 3084
Public contact	Michele Sallaberger, The Florey Institute of Neuroscience and Mental Health, 61 390357269, michele.sallaberger@florey.edu.au
Scientific contact	Michele Sallaberger, The Florey Institute of Neuroscience and Mental Health, 61 390357269, michele.sallaberger@florey.edu.au

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	19 April 2024
Is this the analysis of the primary completion data?	Yes
Primary completion date	28 May 2023
Global end of trial reached?	Yes
Global end of trial date	28 May 2023
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To determine the efficacy and safety of administration of intravenous tranexamic acid in patients with intracerebral haemorrhage within 2 hours of onset.

Protection of trial subjects:

Informed consent

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 July 2017
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Finland: 18
Country: Number of subjects enrolled	Australia: 145
Country: Number of subjects enrolled	Taiwan: 38
Worldwide total number of subjects	201
EEA total number of subjects	18

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)	0
Adults (18-64 years)	201
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details: -

Pre-assignment period milestones

Number of subjects started	202 ^[1]
Number of subjects completed	201

Pre-assignment subject non-completion reasons

Reason: Number of subjects	Consent withdrawn by subject: 1
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Notes:

[1] - The number of subjects reported to have started the pre-assignment period are not the same as the worldwide number enrolled in the trial. It is expected that these numbers will be the same.

Justification: 1 patient withdrew consent

Period 1

Period 1 title	Baseline
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Monitor, Carer, Assessor

Arms

Are arms mutually exclusive?	Yes
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Arm title	Tranexamic acid
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Arm description: -

Arm type	Experimental
Investigational medicinal product name	tranexamic acid
Investigational medicinal product code	ATC B02AA02
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Intravenous infusion of 1 g over 10 min followed by 1 g over 8 h

Arm title	Placebo
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Arm description: -

Arm type	Placebo
Investigational medicinal product name	normal saline
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Intravenous infusion of 1 g over 10 min followed by 1 g over 8 h

Number of subjects in period 1	Tranexamic acid	Placebo
Started	103	98
Completed	103	98

Period 2

Period 2 title	24 hour
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Monitor, Carer, Assessor

Arms

Are arms mutually exclusive?	Yes
Arm title	Tranexamic acid

Arm description: -

Arm type	Experimental
Investigational medicinal product name	tranexamic acid
Investigational medicinal product code	ATC B02AA02
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Intravenous infusion of 1 g over 10 min followed by 1 g over 8 h

Arm title	Placebo
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Arm description: -

Arm type	Placebo
Investigational medicinal product name	Normal saline
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Intravenous 1 g over 10 min followed by 1 g over 8 h

Number of subjects in period 2	Tranexamic acid	Placebo
Started	103	98
Completed	103	98

Period 3	
Period 3 title	90 days
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Assessor, Monitor, Carer
Arms	
Are arms mutually exclusive?	Yes
Arm title	Tranexamic acid
Arm description: -	
Arm type	Experimental
Investigational medicinal product name	tranexamic acid
Investigational medicinal product code	ATC B02AA02
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use
Dosage and administration details:	
Intravenous infusion of 1 g over 10 min followed by 1 g over 8 h	
Arm title	Placebo
Arm description: -	
Arm type	Placebo
Investigational medicinal product name	normal saline
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use
Dosage and administration details:	
Intravenous infusion of 1 g over 10 min followed by 1 g over 8 h	

Number of subjects in period 3	Tranexamic acid	Placebo
Started	103	98
Completed	103	98

Baseline characteristics

Reporting groups

Reporting group title	Tranexamic acid
Reporting group description: -	
Reporting group title	Placebo
Reporting group description: -	

Reporting group values	Tranexamic acid	Placebo	Total
Number of subjects	103	98	201
Age categorical Units: Subjects			
In utero			0
Preterm newborn infants (gestational age < 37 wks)			0
Newborns (0-27 days)			0
Infants and toddlers (28 days-23 months)			0
Children (2-11 years)			0
Adolescents (12-17 years)			0
Adults (18-64 years)			0
From 65-84 years			0
85 years and over			0
Age continuous Units: years			
median	65	67	
inter-quartile range (Q1-Q3)	54 to 76	57 to 77	-
Gender categorical Units: Subjects			
Female	40	42	82
Male	63	56	119

End points

End points reporting groups

Reporting group title	Tranexamic acid
Reporting group description: -	
Reporting group title	Placebo
Reporting group description: -	
Reporting group title	Tranexamic acid
Reporting group description: -	
Reporting group title	Placebo
Reporting group description: -	
Reporting group title	Tranexamic acid
Reporting group description: -	
Reporting group title	Placebo
Reporting group description: -	

Primary: Haematoma growth

End point title	Haematoma growth
End point description:	
End point type	Primary
End point timeframe:	
24 hours	

End point values	Tranexamic acid	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	103	98		
Units: Haematoma growth	43	37		

Statistical analyses

Statistical analysis title	Primary outcome
Comparison groups	Tranexamic acid v Placebo
Number of subjects included in analysis	201
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.37
Method	Regression, Logistic
Parameter estimate	Risk difference (RD)
Point estimate	0.06

Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.07
upper limit	0.19

Adverse events

Adverse events information^[1]

Timeframe for reporting adverse events:

90 days

Assessment type	Systematic
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Dictionary used

Dictionary name	NA
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Dictionary version	0
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Reporting groups

Reporting group title	Tranexamic acid
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Reporting group description: -

Reporting group title	Placebo
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Reporting group description: -

Notes:

[1] - There are no non-serious adverse events recorded for these results. It is expected that there will be at least one non-serious adverse event reported.

Justification: NA

Serious adverse events	Tranexamic acid	Placebo	
Total subjects affected by serious adverse events			
subjects affected / exposed	22 / 103 (21.36%)	16 / 98 (16.33%)	
number of deaths (all causes)	19	15	
number of deaths resulting from adverse events			
Vascular disorders			
Major thromboembolic events			
subjects affected / exposed	3 / 103 (2.91%)	1 / 98 (1.02%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Death			
subjects affected / exposed	19 / 103 (18.45%)	15 / 98 (15.31%)	
occurrences causally related to treatment / all	0 / 19	0 / 15	
deaths causally related to treatment / all	0 / 19	0 / 15	

Frequency threshold for reporting non-serious adverse events: 0 %

Non-serious adverse events	Tranexamic acid	Placebo	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 103 (0.00%)	0 / 98 (0.00%)	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
15 October 2020	Version 6.0, 15 October 2020

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported

Online references

<http://www.ncbi.nlm.nih.gov/pubmed/38648814>