Clinical trial results:
Ensayo clínico multicéntrico, aleatorizado y controlado con placebo para evaluar la eficacia de la utilización perioperatoria de ácido tranexámico sobre la hemorragia quirúrgica en la cirugía compleja de columna.

Clinical trial, multicenter, randomized and placebo controlled to evaluate the efficacy of the peri-operative use of tranexamic acid on surgical bleeding in major spinal surgery

Summary

EudraCT number	2008-006938-94
Trial protocol	ES
Global end of trial date	29 May 2014

Results information

Result version number	v1 (current)
This version publication date	21 November 2021
First version publication date	21 November 2021

Trial information

Trial identification

Sponsor protocol code	TRANEX2009

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01136590
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	VHIR
Sponsor organisation address	Passeig Vall Hebron 119-129, Barcelona, Spain, 08035
Public contact	Joaquin Lopez-Soriano, VHIR, joaquin.lopez.soriano@vhir.org
Scientific contact	Maria José Colomina Soler, VHIR, mjcolomina@vhebron.net

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	29 May 2014
Is this the analysis of the primary completion data?	Yes
Primary completion date	29 May 2014
Global end of trial reached?	Yes
Global end of trial date	29 May 2014
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

This study was designed to investigate the hypothesis that TXA reduces perioperative blood loss and transfusion requirements in patients undergoing major spine procedures.

Protection of trial subjects:

Preoperative administration of i.v. iron or erythropoietin to optimise the haemoglobin concentrations was recorded. All centres used the same protocol for this purpose.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 September 2010
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	Spain: 96
Worldwide total number of subjects	96
EEA total number of subjects	96

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)	50
From 65 to 84 years	46
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Patients were recruited at Hospital Clínic (Barcelona), Hospital Universitari Bellvitge (Barcelona), Hospital Universitari Vall d'Hebron (Barcelona), and Hospital de Getafe (Madrid, Spain).

Pre-assignment

Screening details: -

Pre-assignment period milestones

Number of subjects started	96
Number of subjects completed	96

Period 1

Period 1 title	All the study (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Arms

Are arms mutually exclusive?	Yes
Arm title	TXA iv

Arm description:

TXA administration

Arm type	Experimental
Investigational medicinal product name	Tranexamic acid
Investigational medicinal product code	
Other name	Amchafibrin
Pharmaceutical forms	Suspension for injection
Routes of administration	Intravenous use

Dosage and administration details:

Intravenous infusion of 10mg/kg was administered for 20min before the surgical incision, followed by perfusion of 2mg/kg up tosurgical wound closure at completion of surgery.

Arm title	Placebo

Arm description: -

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

Dosage and administration details:

Same volume than TXA group

Number of subjects in period 1	TXA iv	Placebo
Started	44	52
Completed	44	51
Not completed	0	1
Consent withdrawn by subject	-	1

Baseline characteristics

Reporting groups

Reporting group title	All the study

Reporting group description: -

Reporting group values	All the study	Total	
Number of subjects	96	96	
Age categorical Units: Subjects			
Adults (18-64 years)	20	20	
From 65-84 years	76	76	
Age continuous Units: years			
arithmetic mean	54.5		
full range (min-max)	18 to 75	-	
Gender categorical Units: Subjects			
Female	67	67	
Male	29	29	

Subject analysis sets

Subject analysis set title	TXA vs placebo
Subject analysis set type	Full analysis

Subject analysis set description:
TXA vs placebo comparison

Reporting group values	TXA vs placebo		
Number of subjects	95		
Age categorical Units: Subjects			
Adults (18-64 years)	20		
From 65-84 years	75		
Age continuous Units: years			
arithmetic mean	54.5		
full range (min-max)	18 to 75		
Gender categorical Units: Subjects			
Female	66		
Male	29		

End points

End points reporting groups	
Reporting group title	TXA iv
Reporting group description: TXA administration	
Reporting group title	Placebo
Reporting group description: -	
Subject analysis set title	TXA vs placebo
Subject analysis set type	Full analysis
Subject analysis set description: TXA vs placebo comparison	

Primary: Total number of transfusion units required	
End point title	Total number of transfusion units required
End point description:	
End point type	Primary
End point timeframe: Up to postoperative day seven	

End point values	TXA iv	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	44	51		
Units: Units				
number (confidence interval 95%)	0.85 (0.54 to 1.33)	1.42 (0.97 to 2.08)		

Statistical analyses

Statistical analysis title	RBC units
Comparison groups	TXA iv v Placebo
Number of subjects included in analysis	95
Analysis specification	Post-hoc
Analysis type	superiority
P-value	= 0.06
Method	t-test, 2-sided
Parameter estimate	Geometrical mean

Secondary: Total Blood loss	
End point title	Total Blood loss

End point description:

End point type	Secondary

End point timeframe:

Up to postoperative day seven

End point values	TXA iv	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	44	51		
Units: millilitre(s)				
number (confidence interval 95%)	1695 (1499 to 1916)	2112 (1878 to 2375)		

Statistical analyses

Statistical analysis title	TBL ml
Comparison groups	TXA iv v Placebo
Number of subjects included in analysis	95
Analysis specification	Post-hoc
Analysis type	superiority
P-value	= 0.01
Method	t-test, 2-sided
Parameter estimate	Geometrical mean

Secondary: Intraoperative blood loss

End point title	Intraoperative blood loss

End point description:

End point type	Secondary

End point timeframe:

Up to postoperative day seven

End point values	TXA iv	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	44	51		
Units: millilitre(s)				
geometric mean (confidence interval 95%)	1695 (1499 to 1916)	2112 (1878 to 2375)		

Statistical analyses

Statistical analysis title	TBL ml
Comparison groups	TXA iv v Placebo
Number of subjects included in analysis	95
Analysis specification	Post-hoc
Analysis type	superiority
P-value	= 0.01
Method	t-test, 2-sided
Parameter estimate	Geometrical mean

Adverse events

Adverse events information	
Timeframe for reporting adverse events:	
During all the study	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	14.1

Reporting groups	
Reporting group title	TXA iv
Reporting group description: -	
Reporting group title	Placebo
Reporting group description: -	

Serious adverse events	TXA iv	Placebo	
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 44 (4.55%)	1 / 51 (1.96%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	
Vascular disorders			
Venous thromboembolism			
subjects affected / exposed	2 / 44 (4.55%)	1 / 51 (1.96%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
Cholecystitis			
subjects affected / exposed	0 / 44 (0.00%)	1 / 51 (1.96%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	TXA iv	Placebo	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	24 / 44 (54.55%)	31 / 51 (60.78%)	
Hepatobiliary disorders			

Liver function parameters subjects affected / exposed occurrences (all)	24 / 44 (54.55%) 24	31 / 51 (60.78%) 31	
Renal and urinary disorders Impaired renal function subjects affected / exposed occurrences (all)	2 / 44 (4.55%) 2	0 / 51 (0.00%) 0	

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

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

Further studies are needed to find the optimal TXA dose, with attention to the pharmacokinetics of this drug

Notes:

Online references

http://www.ncbi.nlm.nih.gov/pubmed/28203735