Clinical trial results:
Prospective Multi-Center Evaluation of the Duration of Therapy for Thrombosis in Children

Summary

EudraCT number	2015-001776-21
Trial protocol	AT NL
Global end of trial date	31 December 2021

Results information

Result version number	v1 (current)
This version publication date	08 October 2023
First version publication date	08 October 2023

Trial information

Trial identification

Sponsor protocol code	NCT00687882

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT00687882
WHO universal trial number (UTN)	-
Other trial identifiers	Kids-DOTT: KidsDOTT

Notes:

Sponsors

Sponsor organisation name	Medizinische Universität Wien
Sponsor organisation address	Spitalgasse 23, Wien, Austria, 1090
Public contact	Univ. Prof. Dr. , M.Sc Christoph Male, Medizinische Universität Wien, Universitätsklinik für Kinder- und Jugendheilkunde, 0043 14040021100, christoph.male@meduniwien.ac.at
Scientific contact	Univ. Prof. Dr. , M.Sc Christoph Male, Medizinische Universität Wien, Universitätsklinik für Kinder- und Jugendheilkunde, 0043 14040021100, christoph.male@meduniwien.ac.at

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	01 April 2021
Is this the analysis of the primary completion data?	Yes
Primary completion date	31 January 2021
Global end of trial reached?	Yes
Global end of trial date	31 December 2021
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To evaluate the efficacy and safety of shortened-duration (6 weeks total) versus conventional-duration (3 months total) anticoagulation for first-episode, provoked, acute venous thrombosis among children in whom thrombus resolution/non-occlusion (i.e. established blood flow) is evident after the initial 6 weeks of anticoagulant therapy
Hypothesis: Among children with first-episode, provoked, acute venous thrombosis in whom thrombosis is resolved or non-occlusive at six weeks follow-up, a shortened duration of anticoagulation (total six weeks; i.e. no further therapy) is non-inferior in efficacy to the conventional duration (total three months) of anticoagulation with respect to the risk of symptomatic recurrent VTE at 1 year, and is superior in safety with respect to the risk of clinically-relevant bleeding.(The hypothesis will also be tested in secondary analysis at 2 years, using the same efficacy and safety outcomes as for the 1 year primary analysis.)

Protection of trial subjects:

yes

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	30 November 2008
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	Austria: 6
Worldwide total number of subjects	6
EEA total number of subjects	6

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)	1
Children (2-11 years)	2
Adolescents (12-17 years)	3

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

Subject disposition

Recruitment

Recruitment details:

Children (birth to < 21a) with acute deep venous thrombosis in the past 30 days

Pre-assignment

Screening details:

children with provoked event (central venous line, infection,dehydration, surgery, trauma...)

Period 1

Period 1 title	baseline (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Arm title	Duration of anticoagulant therapy

Arm description:

duration (6 or 12 weeks total)

Arm type	Active comparator
Investigational medicinal product name	Marcoumar
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Coated tablet
Routes of administration	Oral use

Dosage and administration details:

depending on patients INR value

Investigational medicinal product name	Lovenox
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

depending on patients anti Xa value

Number of subjects in period 1	Duration of anticoagulant therapy
Started	6
Completed	5
Not completed	1
Adverse event, serious fatal	1

Baseline characteristics

Reporting groups	
Reporting group title	Duration of anticoagulant therapy
Reporting group description: duration (6 or 12 weeks total)	

Reporting group values	Duration of anticoagulant therapy	Total	
Number of subjects	6	6	
Age categorical Units: Subjects			
In utero	0	0	
Preterm newborn infants (gestational age < 37 wks)	0	0	
Newborns (0-27 days)	1	1	
Infants and toddlers (28 days-23 months)	2	2	
Children (2-11 years)	0	0	
Adolescents (12-17 years)	3	3	
Adults (18-64 years)	0	0	
From 65-84 years	0	0	
85 years and over	0	0	
Gender categorical Units: Subjects			
Female	2	2	
Male	4	4	

Subject analysis sets	
Subject analysis set title	Marcoumar
Subject analysis set type	Intention-to-treat
Subject analysis set description: 6 weeks duration of anticoagulant thearpy	
Subject analysis set title	Marcoumar
Subject analysis set type	Intention-to-treat
Subject analysis set description: 12 weeks duration of anticoagulant therapy	
Subject analysis set title	Lovenox
Subject analysis set type	Intention-to-treat
Subject analysis set description: duration of anticoagulant therapy 6 weeks	

Reporting group values	Marcoumar	Marcoumar	Lovenox
Number of subjects	5	3	1
Age categorical Units: Subjects			
In utero	0	0	0

Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	1
Infants and toddlers (28 days-23 months)	2	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	3	3	0
Adults (18-64 years)	0	0	0
From 65-84 years	0	0	0
85 years and over	0	0	0
Gender categorical			
Units: Subjects			
Female	2	2	0
Male	3	1	1

End points

End points reporting groups

Reporting group title	Duration of anticoagulant therapy
Reporting group description: duration (6 or 12 weeks total)	
Subject analysis set title	Marcoumar
Subject analysis set type	Intention-to-treat
Subject analysis set description: 6 weeks duration of anticoagulant thearpy	
Subject analysis set title	Marcoumar
Subject analysis set type	Intention-to-treat
Subject analysis set description: 12 weeks duration of anticoagulant therapy	
Subject analysis set title	Lovenox
Subject analysis set type	Intention-to-treat
Subject analysis set description: duration of anticoagulant therapy 6 weeks	

Primary: Occurrence of symptomatic recurrent VTE within 1 year

End point title	Occurrence of symptomatic recurrent VTE within 1 year[1]
End point description:	
End point type	Primary
End point timeframe: 1 year	

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: statistical analyses were performed at John Hopkins All children`s Hospital (St. Petersburg, FL, USA)

End point values	Marcoumar	Marcoumar	Lovenox	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	5	3	1	
Units: thrombotic events	0	0	0	

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]	
Timeframe for reporting adverse events: until follow up visit after 1 year	
Assessment type	Non-systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	24.1

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

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: No AEs occurred in relation with medication

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
11 July 2019	changes to protocol, ICF,screening log, Manual of Operations and recruitment brochure

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported