Clinical trial results:
Does staphylothrombin enhance coagulation activation in staphylococcus aureus bacteremia?

Summary

EudraCT number	2009-009056-20
Trial protocol	AT
Global end of trial date	11 May 2013

Results information

Result version number	v1 (current)
This version publication date	
First version publication date	

Trial information

Trial identification

Sponsor protocol code	1.0

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Medical University of Vienna
Sponsor organisation address	Währinger Gürtel 18-20, Vienna, Austria, 1090
Public contact	Department of Clinical Pharmacology, Department of Clinical Pharmacology, 0043 14040029810, klin-pharmakologie@meduniwien.ac.at
Scientific contact	Department of Clinical Pharmacology , Department of Clinical Pharmacology, 0043 14040029810, klin-pharmakologie@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	
Is this the analysis of the primary	Yes

completion data?	
Primary completion date	11 May 2013
Global end of trial reached?	Yes
Global end of trial date	11 May 2013
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary aim of the study is to investigate, whether the oral direct thrombin inhibitor dabigatran reduces in vivo parameter of coagulation activation more effectively than subcutaneous injections of enoxaparin in patients with staphylococcus aureus bacteremia.

Protection of trial subjects:

Subjects were during the trail under the supervision of a physician or an experienced nurse.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	
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	Austria: 71
Worldwide total number of subjects	71
EEA total number of subjects	71

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)	43
From 65 to 84 years	26
85 years and over	2

Subject disposition

Recruitment

Recruitment details:

Subjects were recruited by use of the data base of the Clinical Pharmacology, Medical University of Vienna.

Pre-assignment

Screening details:

Check of the in- and exclusion criteria, physical examination, vital signs, laboratory assessment

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Dabigatran

Arm description:

After baseline blood sampling patients with staph. aureus bacteremia will be randomly assigned to receive dabigatran.

Arm type	Experimental
Investigational medicinal product name	Dabigatran
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

The dose will be standard dose: 220mg daily, taken as 1x 2 capsules of 110mg p.o. for a maximum of 4 days. In unconscious patients Dabigatran will be administered by gavage.

Arm title	Enoxaparin-Sodium

Arm description:

After baseline blood sampling patients with staph. aureus bacteremia will be randomly assigned to receive enoxaparin.

Arm type	Active comparator
Investigational medicinal product name	Enoxaparin-Sodium
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

40mg as a daily subcutaneous injection are standard care for the prophylaxis of VTE in medical patients bedridden due to acute illness

Number of subjects in period 1	Dabigatran	Enoxaparin-Sodium
Started	9	62
Completed	9	60
Not completed	0	2
Physician decision	-	2

Baseline characteristics

Reporting groups	
Reporting group title	Overall trial

Reporting group description: -

Reporting group values	Overall trial	Total	
Number of subjects	71	71	
Age categorical Units: Subjects			
In utero	0	0	
Preterm newborn infants (gestational age < 37 wks)	0	0	
Newborns (0-27 days)	0	0	
Infants and toddlers (28 days-23 months)	0	0	
Children (2-11 years)	0	0	
Adolescents (12-17 years)	0	0	
Adults (18-64 years)	43	43	
From 65-84 years	26	26	
85 years and over	2	2	
Gender categorical Units: Subjects			
Female	31	31	
Male	40	40	

End points

End points reporting groups

Reporting group title	Dabigatran
Reporting group description:	
After baseline blood sampling patients with staph. aureus bacteremia will be randomly assigned to receive dabigatran.	
Reporting group title	Enoxaparin-Sodium
Reporting group description:	
After baseline blood sampling patients with staph. aureus bacteremia will be randomly assigned to receive enoxaparin.	

Adverse events

Adverse events information	
Timeframe for reporting adverse events: 13.08.2009-11.05.2013	
Assessment type	Systematic
Dictionary used	
Dictionary name	MedDRA
Dictionary version	22.1

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

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
28 July 2009	Amendment to ICON and study protocol

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported