Clinical trial results:
Pharmacokinetic/Pharmacodynamic effects of add-on antiplatelet therapy with parenteral cangrelor as compared to standard dual antiplatelet treatment in patients with ST-elevation myocardial infarction complicated by out-of-hospital cardiac arrest and treated with targeted temperature management – A Randomized Controlled Trial

Summary

EudraCT number	2016-003265-26
Trial protocol	AT
Global end of trial date	12 November 2019

Results information

Result version number	v1 (current)
This version publication date	28 April 2023
First version publication date	28 April 2023

Trial information

Trial identification

Sponsor protocol code	345

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	Spitalgasse 23, Vienna, Austria, 1090
Public contact	Department of Emergency Medicine, Medical University of Vienna, +43 4040039530, gabriela.hess@meduniwien.ac.at
Scientific contact	Department of Emergency Medicine, Medical University of Vienna, +43 4040039530, gabriela.hess@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	27 November 2019
Is this the analysis of the primary completion data?	Yes
Primary completion date	12 November 2019
Global end of trial reached?	Yes
Global end of trial date	12 November 2019
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

To assess the additive platelet suppressing effect of iv P2Y12r inhibitor cangrelor in cardiac arrest patients with STEMI. In particular, the trial aims to investigate whether the additional iv infusion of cangrelor (as "on top treatment") is superior (i.e. stronger and faster) to the standard oral P2Y12r inhibitor regimen in terms of suppressing ADP-dependent platelet activation at the time of cardiac intervention (i.e. stent placement) in out-of-hospital cardiac arrest (OHCA) patients with STEMI treated with therapeutic hypothermia (TH).

Protection of trial subjects:

not applicable

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	09 January 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	Austria: 16
Worldwide total number of subjects	16
EEA total number of subjects	16

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)	14
From 65 to 84 years	2
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

We screened all patients admitted to the emergency department of the medical university of vienna for CPR due to suspected ACS

Pre-assignment

Screening details:

not applicable

Period 1

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

Blinding implementation details:

observational study only

Arms

Arm title	Cangrelor Arm

Arm description:

observational part

Arm type	Experimental
Investigational medicinal product name	Cangrelor
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

30µg/kg intravenous bolus, 4µg/kg/min continuous infusion

Number of subjects in period 1	Cangrelor Arm
Started	16
Completed	16

Baseline characteristics

Reporting groups	
Reporting group title	Recruitment Period

Reporting group description: -

Reporting group values	Recruitment Period	Total	
Number of subjects	16	16	
Age categorical Units: Subjects			
Adults (18-64 years)	14	14	
From 65-84 years	2	2	
Age continuous Units: years			
median	58		
inter-quartile range (Q1-Q3)	46 to 61	-	
Gender categorical Units: Subjects			
Female	3	3	
Male	13	13	

End points

End points reporting groups

Reporting group title	Cangrelor Arm
Reporting group description: observational part	

Primary: patients with HPR at predefined time points during the first 24 hours after cangrelor cessation

End point title	patients with HPR at predefined time points during the first 24 hours after cangrelor cessation[1]
End point description:	
End point type	Primary
End point timeframe: 24h after cangrelor cessation	

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: Only descriptive analysis for primary endpoint, no between group comparison

End point values	Cangrelor Arm			
Subject group type	Reporting group			
Number of subjects analysed	16			
Units: number	7			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]	
Timeframe for reporting adverse events: until hospital discharge	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	22.1

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

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 adverse events in relation to study drug

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

Online references

http://www.ncbi.nlm.nih.gov/pubmed/32098088