Clinical trial results:
Evaluation of the effects and plasma concentration of the potent platelet inhibitor ticagrelor, after crushed and non-crushed intake, after semi-urgent coronary bypass and in patients after cardiac arrest.

Summary

EudraCT number	2013-004191-35
Trial protocol	BE
Global end of trial date	06 December 2019

Results information

Result version number	v1 (current)
This version publication date	08 August 2024
First version publication date	08 August 2024
Summary attachment (see zip file)	Final Study Report (2013-004191-35_Ticagrelor_Final_Study_Report.pdf)

Trial information

Trial identification

Sponsor protocol code	AGO/2013/011

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Ghent University Hospital
Sponsor organisation address	C. Heymanslaan 10, Gent, Belgium, 9000
Public contact	Bimetra Clinics, Ghent University Hospital, +32 93320500, Bimetra.Clinics@uzgent.be
Scientific contact	Bimetra Clinics, Ghent University Hospital, 093321539 93320500, Bimetra.Clinics@uzgent.be

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	08 June 2021
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	06 December 2019
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The first aim of the study is to prove that after starting the therapy with crushed tablets, the platelet inhibition will be as expected after starting therapy with intact tablets.

Protection of trial subjects:

See attachment Final Study Report

Background therapy:

See attachment Final Study Report

Evidence for comparator:

See attachment Final Study Report

Actual start date of recruitment	01 December 2014
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	Belgium: 40
Worldwide total number of subjects	40
EEA total number of subjects	40

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)	40
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

See attachment Final Study Report

Pre-assignment

Screening details:

See attachment Final Study Report

Period 1

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

Blinding implementation details:

See attachment Final Study Report

Arms

Are arms mutually exclusive?	Yes
Arm title	Arm 1

Arm description:

See attachment Final Study Report

Arm type	Active comparator
Investigational medicinal product name	Ticagrelot
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

See attachment Final Study Report

Arm title	Arm 2

Arm description:

See attachment Final Study Report

Arm type	Active comparator
Investigational medicinal product name	Ticagrelot
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

See attachment Final Study Report

Number of subjects in period 1	Arm 1	Arm 2
Started	20	20
Completed	20	20

Baseline characteristics

End points

End points reporting groups

Reporting group title	Arm 1
Reporting group description:	
See attachment Final Study Report	
Reporting group title	Arm 2
Reporting group description:	
See attachment Final Study Report	

Primary: Primary

End point title	Primary[1]
End point description:	
End point type	Primary
End point timeframe:	
See attachment Final Study Report	

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: See attachment Final Study Report

End point values	Arm 1	Arm 2		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	20	20		
Units: seconds				
number (not applicable)	20	20		

Statistical analyses

No statistical analyses for this end point

Secondary: Secondary

End point title	Secondary
End point description:	
End point type	Secondary
End point timeframe:	
See attachment Final Study Report	

End point values	Arm 1	Arm 2		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	20	20		
Units: Mg				
number (not applicable)	20	20		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]	
Timeframe for reporting adverse events: During the study	
Adverse event reporting additional description: See attachment Final Study Report	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	0

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: See attachment Final Study Report

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