Clinical trial results:
Hyperalgesia, Persistent Pain, and Fentanyl Dosing in On-Pump Coronary Artery Bypass Grafting

Summary

EudraCT number	2017-003278-15
Trial protocol	BE
Global end of trial date	09 January 2021

Results information

Result version number	v1 (current)
This version publication date	06 July 2024
First version publication date	06 July 2024
Summary attachment (see zip file)	Final Study Report (BC-73_Final study Report_2022-05-02.pdf)

Trial information

Trial identification

Sponsor protocol code	AGO/2017/005

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 93320530, hiruz.ctu@uzgent.be
Scientific contact	Bimetra Clinics, Ghent University Hospital, +32 93320530, hiruz.ctu@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	28 April 2022
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	09 January 2021
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

to assess whether or not different intraoperative dosing schemes of fentanyl during on-pump CABG surgery influence the area of hyperalgesia as measured by sternal pin-prick testing on the first postoperative day.

Protection of trial subjects:

See attachement

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	14 May 2018
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: 66
Worldwide total number of subjects	66
EEA total number of subjects	66

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)	46
From 65 to 84 years	20
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

See attachement

Pre-assignment

Screening details:

See attachement

Period 1

Period 1 title	Overal Trial (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Single blind[1]
Roles blinded	Subject, Carer, Assessor

Blinding implementation details:

See attachement

Arms

Arm title	Arm 1

Arm description:

See attachement

Arm type	See attachement
Investigational medicinal product name	Fentanyl
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for dispersion for injection
Routes of administration	Injection

Dosage and administration details:

See attachement

Notes:

[1] - The number of roles blinded appears inconsistent with a single blinded trial. It is expected that there will be one role blinded in a single blind trial.
Justification: See Attachment

Number of subjects in period 1	Arm 1
Started	66
Completed	66

Baseline characteristics

End points

End points reporting groups

Reporting group title	Arm 1
Reporting group description:	
See attachement	

Primary: Primary

End point title	Primary[1]
End point description:	
End point type	Primary
End point timeframe:	
During the study	

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

End point values	Arm 1			
Subject group type	Reporting group			
Number of subjects analysed	66			
Units: mN				
number (not applicable)	66			

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:	
During the study	

End point values	Arm 1			
Subject group type	Reporting group			
Number of subjects analysed	66			
Units: Subjects	66			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]	
Timeframe for reporting adverse events:	
During the study	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	0

Frequency threshold for reporting non-serious adverse events: 3 %

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

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