Clinical trial results:
Comparison of pain and comfort in patients following cardiac surgery: opioid-morphine managed vs multimodal pain-management.

Summary

EudraCT number	2019-000515-84
Trial protocol	BE
Global end of trial date	03 December 2021

Results information

Result version number	v1 (current)
This version publication date	02 August 2024
First version publication date	02 August 2024
Summary attachment (see zip file)	Final Study Report (2019-000515-84_FinalStudyReport.pdf)

Trial information

Trial identification

Sponsor protocol code	AGO/2019/001

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT04987372
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	UZ Gent - HIRUZ
Sponsor organisation address	C. Heymanslaan 10, Gent, Belgium, 9000
Public contact	HIRUZ CTU, Ghent University Hospital, 32 093320530, hiruz.ctu@uzgent.be
Scientific contact	HIRUZ CTU, Ghent University Hospital, 093320530 093320530, 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	09 December 2022
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	03 December 2021
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To compare "Fentanyl-Tramadol-Paracetamol-Oxycodon" regimen to a multimodal painmanagement "pregabalin-minimal fentanyl-ketamine-lidocain-dexmedetomidine-paracetamol" to determin which therapy provides the most comfort, the fastest extubation time, the least pain and the least delirium.

Protection of trial subjects:

The risks of the multimodal therapy can be estimated low, as the dosing regimen of the products is low. This low dosing is because of synergistic analgesic actions.
Intensive care unit (ICU) equipment includes patient monitoring, respiratory and cardiac support, pain management , emergency resuscitation devices, and other life support equipment designed to care for patients who are seriously injured, have a critical or life-threatening illness, or have undergone a major surgical procedure, thereby requiring 24-hour care and monitoring.
Patient monitoring equipment following cardiac surgery includes the following:
- Acute care physiologic monitoring system—comprehensive patient monitoring systems that can be configured to continuously measure and display a number of parameters via electrodes and sensors that are connected to the patient. These may include the electrical activity of the heart via an EKG, respiration rate (breathing), blood pressure, body temperature, cardiac output, and amount of oxygen and carbon dioxide in the blood. Each patient bed in an ICU has a physiologic monitor that measure these body activities.
- Pulse oximeter—monitors the arterial hemoglobin oxygen saturation (oxygen level) of the patient's blood with a sensor clipped over the finger or toe.
- Apnea monitor—continuously monitors breathing via electrodes or sensors placed on the patient. An apnea monitor detects cessation of breathing in infants and adults at risk of respiratory failure, displays respiration parameters, and triggers an alarm if a certain amount of time passes without a patient's breath being detected. Apnea monitoring may be a capability included in a physiologic monitor.
- The process of analysis and monitoring of arterial blood gas is an essential part of diagnosing and managing the oxygenation status and acid–base balance of patients during and following cardiac surgery in the operation room and in the Intensive Care Unit.
- Pain and agitation scales are standar

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	17 June 2019
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: 96
Worldwide total number of subjects	96
EEA total number of subjects	96

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)	0
From 65 to 84 years	96
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	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Carer, Assessor

Blinding implementation details:

See attachment Final Study Report

Arms

Are arms mutually exclusive?	Yes
Arm title	Classic

Arm description:

See attachment Final Study Report

Arm type	No intervention

No investigational medicinal product assigned in this arm

Arm title	Multimodal

Arm description:

See attachment Final Study Report

Arm type	Active comparator
Investigational medicinal product name	Pregabiline
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Infusion

Dosage and administration details:

See attachment Final Study Report

Number of subjects in period 1	Classic	Multimodal
Started	50	46
Completed	50	46

Baseline characteristics

End points

End points reporting groups

Reporting group title	Classic
Reporting group description:	
See attachment Final Study Report	
Reporting group title	Multimodal
Reporting group description:	
See attachment Final Study Report	

Primary: Primary

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

End point values	Classic	Multimodal		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	50	46		
Units: NRS Scale				
number (not applicable)	50	46		

Statistical analyses

No statistical analyses for this end point

Secondary: Secondary

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

End point values	Classic	Multimodal		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	50	46		
Units: ICDSC Score				
number (not applicable)	50	46		

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: 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