



Clinical trial results:

Safety and Efficacy of Patient Controlled Analgesia using the Sublingual Sufentanil Tablet System (SSTS) in a fast track rehabilitation program after Total Knee Arthroplasty.

Summary

EudraCT number	2019-001232-59
Trial protocol	BE
Global end of trial date	19 September 2021

Results information

Result version number	v1 (current)
This version publication date	07 June 2024
First version publication date	07 June 2024
Summary attachment (see zip file)	Protocol (PROTOCOL v 1.0 11 03 2019.docx) Final Study Report (2019-001232-59_Final_Study_Report_Zalviso.pdf)

Trial information

Trial identification

Sponsor protocol code	AGO/2019/002
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Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	UZ Ghent
Sponsor organisation address	C. Heymanslaan 10, Gent, Belgium, 9000
Public contact	HIRUZ CTU, Ghent University Hospital, +32 93320500, Hiruz.ctu@uzgent.be
Scientific contact	HIRUZ CTU, Ghent University Hospital, 093320000 93320500, 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	16 March 2023
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	19 September 2021
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Efficiency of Sublingual Sufentanil Tablet System (SSTS) which is defined as 75% or more of the treated patients proves NRS less than 4 during 48 hours postoperatively, additionally to the basic pain treatment (paracetamol and NSAID).

Protection of trial subjects:

See attachments

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 January 2020
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: 90
Worldwide total number of subjects	90
EEA total number of subjects	90

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)	55
From 65 to 84 years	35
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

See attachments

Period 1

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

Blinding implementation details:

see attachment

Arms

Arm title	Arm A
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Arm description: -

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

Dosage and administration details:

Start administration medication at request of the patient or NRS \geq 4

T0 : 20 minutes after first use of PCA STSS at PACU

Stop administration medication : at 48 hours postoperatively, for comfort reasons it can be continued until 72 hours postoperatively

Number of subjects in period 1	Arm A
Started	90
Completed	90

Baseline characteristics

Reporting groups

Reporting group title

Period

Reporting group description: -

Reporting group values	Period	Total	
Number of subjects	90	90	
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)	0	0	
From 65-84 years	55	55	
85 years and over	35	35	
Gender categorical			
Units: Subjects			
Female	44	44	
Male	46	46	

End points

End points reporting groups

Reporting group title	Arm A
Reporting group description: -	

Primary: Main

End point title	Main ^[1]
End point description:	

End point type	Primary
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End point timeframe:

Cumulative/total time when NRS<4 during 48 hours postoperatively – after 48 hours postoperatively
Length of hospital stay – after the patient discharge
Nausea, vomiting, itching, drowsiness, constipation, desaturation – up to 72 hours postoperatively
E

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 attachments

End point values	Arm A			
Subject group type	Reporting group			
Number of subjects analysed	90			
Units: Subjects	90			

Statistical analyses

No statistical analyses for this end point

Secondary: Secondary

End point title	Secondary
End point description:	

End point type	Secondary
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End point timeframe:

Cumulative/total time when NRS<4 during 48 hours postoperatively – after 48 hours postoperatively
Length of hospital stay – after the patient discharge
Nausea, vomiting, itching, drowsiness, constipation, desaturation – up to 72 hours postoperatively
E

End point values	Arm A			
Subject group type	Reporting group			
Number of subjects analysed	90			
Units: Subjects	90			

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
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	0
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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 attachments

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