Clinical trial results:
The effect of deep neuromuscular block and reversal with sugammadex on surgical conditions and perioperative morbidity in shoulder surgery using a deltopectoral approach

Summary

EudraCT number	2018-002961-21
Trial protocol	BE
Global end of trial date	12 November 2024

Results information

Result version number	v1 (current)
This version publication date	03 August 2025
First version publication date	03 August 2025

Trial information

Trial identification

Sponsor protocol code	NS918

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03643913
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	UZ Leuven
Sponsor organisation address	Herestraat, Leuven, Belgium, 3000
Public contact	Clinical Trial Assistant, UZ Leuven, 32 1634 23 64, traumatologie@uzleuven.be
Scientific contact	Clinical Trial Assistant, UZ Leuven, 32 1634 23 64, traumatologie@uzleuven.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	03 July 2025
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	12 November 2024
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The study evaluates whether deep neuromuscular block during entire surgical procedure to the gleno-humeral joint or the proximal humerus using a deltoideo-pectoral approach results in less muscular damage to the deltoid muscle and therefore less post-operative pain and an earlier functional recovery. The main objective consists of better view and access to the gleno-humeral joint and/or proximal humerus and a decreased early post-operative pain due to less surgical injury to the deltoid muscle.

Protection of trial subjects:

No fault insurance

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	05 November 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: 47
Worldwide total number of subjects	47
EEA total number of subjects	47

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)	35
From 65 to 84 years	12
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Patients at UZ Leuven - Traumatology scheduled for open surgery via the deltopectoral approach (e.g. Latarjet, osteosynthesis, or prosthesis excl. reverse) will be invited to join the study. Daily OR schedules are screened; eligible patients are assessed by a physician and informed consent is obtained.

Period 1

Period 1 title	Overall (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Arms

Are arms mutually exclusive?	Yes
Arm title	Moderate

Arm description: -

Arm type	Active comparator
Investigational medicinal product name	Bridion
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Injection

Dosage and administration details:

2 mg/kg

Arm title	Deep

Arm description: -

Arm type	Experimental
Investigational medicinal product name	Bridion
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intravenous use

Dosage and administration details:

4 mg/kg

Number of subjects in period 1	Moderate	Deep
Started	24	23
Completed	24	23

Baseline characteristics

Reporting groups	
Reporting group title	Moderate
Reporting group description: -	
Reporting group title	Deep
Reporting group description: -	

Reporting group values	Moderate	Deep	Total
Number of subjects	24	23	47
Age categorical Units: Subjects			
Age continuous Units: years			
median	50	56	
inter-quartile range (Q1-Q3)	32.5 to 66	37 to 65	-
Gender categorical Units: Subjects			
Female	9	11	20
Male	15	12	27

End points

End points reporting groups	
Reporting group title	Moderate
Reporting group description: -	
Reporting group title	Deep
Reporting group description: -	

Primary: Surgical conditions	
End point title	Surgical conditions
End point description:	
End point type	Primary
End point timeframe:	
Post-operative	

End point values	Moderate	Deep		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	24	23		
Units: Modified leiden score				
arithmetic mean (standard deviation)	2.75 (± 1.860)	2.43 (± 1.903)		

Statistical analyses

Statistical analysis title	Mann–Whitney U test
Comparison groups	Moderate v Deep
Number of subjects included in analysis	47
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.05
Method	Wilcoxon (Mann-Whitney)

Primary: Post-operative pain	
End point title	Post-operative pain
End point description:	
End point type	Primary
End point timeframe:	
Day 3 post-op	

End point values	Moderate	Deep		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	24	23		
Units: VAS				
arithmetic mean (full range (min-max))	3 (1 to 4)	3 (2 to 4)		

Statistical analyses

Statistical analysis title	Mann–Whitney U test
Comparison groups	Moderate v Deep
Number of subjects included in analysis	47
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.05
Method	Wilcoxon (Mann-Whitney)

Secondary: Muscle damage

End point title	Muscle damage

End point description:

End point type	Secondary

End point timeframe:

Post-operative

End point values	Moderate	Deep		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	24	23		
Units: Deltoid muscle injury				
median (full range (min-max))	2 (1 to 4)	2 (1 to 3)		

Statistical analyses

No statistical analyses for this end point

Secondary: Length of stay at post-anesthesia care unit

End point title	Length of stay at post-anesthesia care unit

End point description:

End point type	Secondary

End point timeframe:

Post-operative

End point values	Moderate	Deep		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	24	23		
Units: Minutes				
median (full range (min-max))	106.5 (60 to 224)	114 (52 to 243)		

Statistical analyses

No statistical analyses for this end point

Secondary: Length of stay at hopsital after surgery

End point title	Length of stay at hopsital after surgery

End point description:

End point type	Secondary

End point timeframe:

Post-operative

End point values	Moderate	Deep		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	24	23		
Units: Days				
median (full range (min-max))	2 (1 to 8)	3 (2 to 8)		

Statistical analyses

No statistical analyses for this end point

Secondary: Surgical time

End point title	Surgical time

End point description:

End point type	Secondary

End point timeframe:
Peri-operative

End point values	Moderate	Deep		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	24	23		
Units: minute				
median (full range (min-max))	69.5 (46 to 163)	76 (38 to 158)		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events:	
Overall	
Assessment type	Systematic

Dictionary used	
Dictionary name	SNOMED CT
Dictionary version	20250301

Reporting groups	
Reporting group title	Moderate
Reporting group description: -	
Reporting group title	Deep
Reporting group description: -	

Serious adverse events	Moderate	Deep	
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 24 (4.17%)	0 / 23 (0.00%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	
Respiratory, thoracic and mediastinal disorders			
Pulmonary embolism and partial atelectasis			
subjects affected / exposed	1 / 24 (4.17%)	0 / 23 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Frequency threshold for reporting non-serious adverse events: 0 %

Non-serious adverse events	Moderate	Deep	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	2 / 24 (8.33%)	3 / 23 (13.04%)	
Vascular disorders			
High blood pressure			
subjects affected / exposed	0 / 24 (0.00%)	1 / 23 (4.35%)	
occurrences (all)	0	1	
Surgical and medical procedures			

Higher doses bridion needed than anticipated			
subjects affected / exposed	0 / 24 (0.00%)	1 / 23 (4.35%)	
occurrences (all)	0	1	
Gastrointestinal disorders			
Nausea			
subjects affected / exposed	1 / 24 (4.17%)	1 / 23 (4.35%)	
occurrences (all)	1	1	
Skin and subcutaneous tissue disorders			
Rash	Additional description: Itchy rash in neck		
subjects affected / exposed	1 / 24 (4.17%)	0 / 23 (0.00%)	
occurrences (all)	1	0	
Psychiatric disorders			
Panic attack	Additional description: Panic attack about numb arm		
subjects affected / exposed	0 / 24 (0.00%)	1 / 23 (4.35%)	
occurrences (all)	0	1	
Musculoskeletal and connective tissue disorders			
Hematoma			
subjects affected / exposed	0 / 24 (0.00%)	1 / 23 (4.35%)	
occurrences (all)	0	1	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
09 November 2018	Raising the maximum age limit from 75 to 85 years to improve patient inclusion.
19 July 2021	This amendment aims to extend the study end date from July 2021 to July 2022.
01 April 2022	The amendment includes a change of PI at UZ Leuven, with Prof. Harm Hoekstra taking over the role from March 14, 2022.
12 March 2024	This amendment aims to extend the study end date from July 2022 to December 31 2024.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? Yes

Date	Interruption	Restart date
13 March 2020	Temporary interruption due to the COVID-19 pandemic.	03 April 2020

Notes:

Limitations and caveats

None reported