Clinical trial results:
Open heart surgery – does it have to hurt that much? PACS – Parasternal After Cardiac Surgery. A prospective randomised study to assess the analgesic effect of a continuous bilateral parasternal block with lidocaine after sternotomy.

Summary

EudraCT number	2018-004672-35
Trial protocol	SE
Global end of trial date	16 July 2022

Results information

Result version number	v1 (current)
This version publication date	26 November 2025
First version publication date	26 November 2025

Trial information

Trial identification

Sponsor protocol code	PACS2019

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Karolinska Institutet
Sponsor organisation address	Nobels väg 6, Solna, Sweden,
Public contact	Mark Larsson, Karolinska University Hospital, Dep of Cardiothoracic Anesthesia and Intensive Care, 46 851770914, mark.larsson@sll.se
Scientific contact	Mark Larsson, Karolinska Institutet, Department of Molecular Medicine and Surgery, 46 851770914, mark.larsson@ki.se

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 July 2022
Is this the analysis of the primary completion data?	Yes
Primary completion date	16 July 2022
Global end of trial reached?	Yes
Global end of trial date	16 July 2022
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The study will test the hypothesis that a continuous bilateral parasternal block with lidocaine will decrease postoperative pain after sternotomy for open cardiac surgery.

Protection of trial subjects:

The trial was approved by the Swedish Ethical Review Authority (registration number 2019e05120) and the Swedish Medical Products Agency (registration number 5.1-2019-78659).

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	07 June 2021
Long term follow-up planned	Yes
Long term follow-up rationale	Safety, Efficacy, Scientific research
Long term follow-up duration	3 Months
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Sweden: 45
Worldwide total number of subjects	45
EEA total number of subjects	45

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)	17
From 65 to 84 years	28

85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Men and non-pregnant women scheduled for elective open heart surgery through a sternotomy at the Karolinska University Hospital were considered for enrolment.

Pre-assignment

Screening details:

Ineligibility: emergency or redo surgery, severe left heart failure, respiratory insufficiency, advanced kidney failure, pronounced hepatic disease, allergy to local anaesthetics, psychiatric disease or any psychoactive medication, cognitive disturbance, or inability to understand instructions, and a history of chronic pain or chronic pain medic.

Period 1

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

Blinding implementation details:

Treatment was randomized in a 1:1 fashion in blocks of eight, except for the last block of five. The trial participants, investigators, attending surgeons, anaesthesiologist, and nurse anaesthetist, and the nurses in the recovery room and surgical ward, were blinded to allocation.

Arms

Are arms mutually exclusive?	Yes
Arm title	Lidocaine

Arm description: -

Arm type	Experimental
Investigational medicinal product name	Lidocaine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection/infusion
Routes of administration	Infusion

Dosage and administration details:

After wound closure at the end of surgery, a multi-hole 19-cm silver-coated catheter (ON-Q Soaker; Avanos Medical, Alpharetta, GA, USA) was inserted on either side of the sternum, under the pectoral muscle and over the costosternal margin. A 20-ml bolus of lidocaine 5 mg/ml was administered through each catheter. Thereafter, an elastomeric pump that contained the allocated treatment provided an infusion of 7 ml/h to each catheter.

Arm title	Saline

Arm description: -

Arm type	Placebo
Investigational medicinal product name	Saline
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection/infusion
Routes of administration	Infusion

Dosage and administration details:

After wound closure at the end of surgery, a multi-hole 19-cm silver-coated catheter (ON-Q Soaker; Avanos Medical, Alpharetta, GA, USA) was inserted on either side of the sternum, under the pectoral muscle and over the costosternal margin. A 20-ml bolus of saline 9 mg/ml (0.9%) was administered through each catheter. Thereafter, an elastomeric pump that contained the allocated treatment provided an infusion of 7 ml/h to each catheter.

Number of subjects in period 1	Lidocaine	Saline
Started	23	22
Completed	13	17
Not completed	10	5
Consent withdrawn by subject	3	1
Adverse event, non-fatal	3	-
Lost to follow-up	4	4

Baseline characteristics

Reporting groups	
Reporting group title	Lidocaine
Reporting group description: -	
Reporting group title	Saline
Reporting group description: -	

Reporting group values	Lidocaine	Saline	Total
Number of subjects	23	22	45
Age categorical Units: Subjects			
In utero			0
Preterm newborn infants (gestational age < 37 wks)			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 65-84 years			0
85 years and over			0
Age continuous Units: years			
median	71	67.5	
inter-quartile range (Q1-Q3)	56 to 74	58 to 71	-
Gender categorical Units: Subjects			
Female	2	3	5
Male	21	19	40
Weight Units: kilogram(s)			
arithmetic mean	75.9	84.5	
standard deviation	± 10.3	± 18.5	-
Height Units: centimetre			
median	178	174.5	
inter-quartile range (Q1-Q3)	170 to 182	169 to 180	-

End points

End points reporting groups	
Reporting group title	Lidocaine
Reporting group description: -	
Reporting group title	Saline
Reporting group description: -	

Primary: Cumulative administration of i.v. PCA morphine at 72 hours	
End point title	Cumulative administration of i.v. PCA morphine at 72 hours
End point description:	
End point type	Primary
End point timeframe:	
Measured at 72h	

End point values	Lidocaine	Saline		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	23	22		
Units: milligram(s)				
median (inter-quartile range (Q1-Q3))	10 (5 to 19)	28.2 (16 to 42.5)		

Statistical analyses

Statistical analysis title	Difference in cumulative morphine in mg
Comparison groups	Saline v Lidocaine
Number of subjects included in analysis	45
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.014
Method	Wilcoxon (Mann-Whitney)

Secondary: Total morphine dose after surgery	
End point title	Total morphine dose after surgery
End point description:	
End point type	Secondary
End point timeframe:	
Post surgery	

End point values	Lidocaine	Saline		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	23	22		
Units: milligram(s)				
median (inter-quartile range (Q1-Q3))	17 (7 to 23)	38.2 (21 to 60.5)		

Statistical analyses

Statistical analysis title	Difference in total morphine in mg
Comparison groups	Lidocaine v Saline
Number of subjects included in analysis	45
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.003
Method	Wilcoxon (Mann-Whitney)

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Start of the intervention until end of follow-up at 3 months.

Assessment type	Systematic

Dictionary used

Dictionary name	NA
Dictionary version	NA

Reporting groups

Reporting group title	Overall study

Reporting group description: -

Serious adverse events	Overall study		
Total subjects affected by serious adverse events			
subjects affected / exposed	16 / 45 (35.56%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Cardiac disorders			
Permanent Pacemaker			
subjects affected / exposed	5 / 45 (11.11%)		
occurrences causally related to treatment / all	5 / 5		
deaths causally related to treatment / all	0 / 0		
Surgical and medical procedures			
Redo bleeding			
subjects affected / exposed	4 / 45 (8.89%)		
occurrences causally related to treatment / all	4 / 4		
deaths causally related to treatment / all	0 / 0		
Nervous system disorders			
Stroke			
subjects affected / exposed	1 / 45 (2.22%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Seizure			
subjects affected / exposed	1 / 45 (2.22%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		

Gastrointestinal disorders			
Ulcus ventriculi/duodeni			
subjects affected / exposed	3 / 45 (6.67%)		
occurrences causally related to treatment / all	3 / 3		
deaths causally related to treatment / all	0 / 0		
Respiratory, thoracic and mediastinal disorders			
Respiratory failure			
subjects affected / exposed	3 / 45 (6.67%)		
occurrences causally related to treatment / all	3 / 3		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Sternal wound infection			
subjects affected / exposed	2 / 45 (4.44%)		
occurrences causally related to treatment / all	2 / 2		
deaths causally related to treatment / all	0 / 0		
Mediastinitis			
subjects affected / exposed	1 / 45 (2.22%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Pneumonia			
subjects affected / exposed	1 / 45 (2.22%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Urinary tract infection			
subjects affected / exposed	2 / 45 (4.44%)		
occurrences causally related to treatment / all	2 / 2		
deaths causally related to treatment / all	0 / 0		

Frequency threshold for reporting non-serious adverse events: 5 %

Non-serious adverse events	Overall study		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	14 / 45 (31.11%)		
Gastrointestinal disorders			

Postoperative nausea and vomiting subjects affected / exposed occurrences (all)	9 / 45 (20.00%) 9		
Psychiatric disorders Not alert subjects affected / exposed occurrences (all)	14 / 45 (31.11%) 14		

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

Online references

http://www.ncbi.nlm.nih.gov/pubmed/38680128