Clinical trial results:
Ropivacain 0,2% plus Dexamethason versus Ropivacain 0,2% plus Placebo in modified pectoral block - A randomized, double-blind, prospective trial

Summary

EudraCT number	2018-003001-26
Trial protocol	AT
Global end of trial date	04 October 2021

Results information

Result version number	v1 (current)
This version publication date	20 February 2023
First version publication date	20 February 2023

Trial information

Trial identification

Sponsor protocol code	1234

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03700177
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Medical University of Innsbruck
Sponsor organisation address	Anichstraße 35, Innsbruck, Austria, 6020
Public contact	Competence Center for Clinical Trials, University Hospital for Anaesthesia and Intensive Care, Anichstrasse 35, 6020 Innsbruck, 0043 512900370086,
Scientific contact	Competence Center for Clinical Trials, University Hospital for Anaesthesia and Intensive Care, Anichstrasse 35, 6020 Innsbruck, 0043 512900370086,

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	04 October 2021
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	04 October 2021
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

to find out if dexamethason added to modified pectoral block (Pecs II) with ropivacaine 0.2% prolongs analgesic effect

Protection of trial subjects:

The visual analogue scale (VAS) to assess pain was assessed on admission to the post-anesthesia care unit (PACU), then hourly during the first 12 hours after PECS II block performance, and then every 12 hours until the end of follow-up after 84 hours. If VAS exceeded a value of 30 mm at any time, even without being actively asked by the medical staff, pain medications according to our study protocol were administered.

Generally spoken - every patient who needs a mastectomy receives a PECS II block - if not refused by the patient. For this study we didn't change the daily routine, neither in the operating theatre nor on the normal ward.

Background therapy:

-

Evidence for comparator:

-

Actual start date of recruitment	07 January 2019
Long term follow-up planned	Yes
Long term follow-up rationale	Efficacy, Scientific research
Long term follow-up duration	12 Months
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Austria: 60
Worldwide total number of subjects	60
EEA total number of subjects	60

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)	34
From 65 to 84 years	22
85 years and over	4

Subject disposition

Recruitment

Recruitment details:

Every friday, our operating theatre manager receives the OP schedule for the next week. Therefore, every friday, we checked the OP schedule for mastectomies in the following week and visited the patients on the day of their arrival in the hospital (usually the day before surgery).

Pre-assignment

Screening details:

Number of patients screened for inclusion were 118. On the day of their arrival in the clinic, they were all checked for eligibility to participate by one of our study members.

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	Subject, Investigator

Arms

Are arms mutually exclusive?	Yes
Arm title	Intervention

Arm description:

Ropivacaine + dexamethasone

Arm type	Active comparator
Investigational medicinal product name	Dexamethasone
Investigational medicinal product code	
Other name	Dexabene
Pharmaceutical forms	Solution for injection
Routes of administration	Perineural use

Dosage and administration details:

For the dexamethasone group, 8 mg dexamethasone (2 ml) was added to 28 ml of ropivacaine 0.2%.

Arm title	Placebo

Arm description:

Ropivacaine + saline solution 0.9%

Arm type	Placebo
Investigational medicinal product name	Saline solution 0.9%
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Perineural use

Dosage and administration details:

For the placebo group, 2 ml of saline solution 0.9% was added to 28 ml of ropivacaine 0.2%.

Number of subjects in period 1	Intervention	Placebo
Started	30	30
Completed	28	30
Not completed	2	0
Did not receive allocated intervention	2	-

Baseline characteristics

Reporting groups	
Reporting group title	Intervention
Reporting group description:	
Ropivacaine + dexamethasone	
Reporting group title	Placebo
Reporting group description:	
Ropivacaine + saline solution 0.9%	

Reporting group values	Intervention	Placebo	Total
Number of subjects	30	30	60
Age categorical			
Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	19	15	34
From 65-84 years	9	13	22
85 years and over	2	2	4
Age continuous			
Units: years			
arithmetic mean	59.0	69.0	
full range (min-max)	51.3 to 74.8	56.0 to 74.0	-
Gender categorical			
female patients undergoing unilateral mastectomy who meet inclusion criteria and want to participate			
Units: Subjects			
Female	30	30	60
Male	0	0	0

End points

End points reporting groups	
Reporting group title	Intervention
Reporting group description: Ropivacaine + dexamethasone	
Reporting group title	Placebo
Reporting group description: Ropivacaine + saline solution 0.9%	

Primary: Total morphine equivalent consumption in the first 72 hours	
End point title	Total morphine equivalent consumption in the first 72 hours
End point description:	
End point type	Primary
End point timeframe: 72 hours	

End point values	Intervention	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	28	30		
Units: mg				
median (standard deviation)	11.89 (± 13.03)	11.90 (± 10.81)		

Statistical analyses

Statistical analysis title	MME - 72 h
Comparison groups	Intervention v Placebo
Number of subjects included in analysis	58
Analysis specification	Pre-specified
Analysis type	equivalence
P-value	= 0.831
Method	Wilcoxon (Mann-Whitney)
Parameter estimate	Median difference (final values)
Confidence interval	
level	95 %

Adverse events

Adverse events information	
Timeframe for reporting adverse events: 84h postoperative	
Assessment type	Systematic
Dictionary used	
Dictionary name	CTCAE
Dictionary version	5.0
Reporting groups	
Reporting group title	Intervention
Reporting group description: Ropivacaine + dexamethasone	
Reporting group title	Placebo
Reporting group description: Ropivacaine + saline solution 0.9%	

Serious adverse events	Intervention	Placebo	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 28 (0.00%)	0 / 30 (0.00%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	

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

Non-serious adverse events	Intervention	Placebo	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	5 / 28 (17.86%)	10 / 30 (33.33%)	
Cardiac disorders			
Hypertension			
subjects affected / exposed	3 / 28 (10.71%)	7 / 30 (23.33%)	
occurrences (all)	10	10	
General disorders and administration site conditions			
Shivering			
subjects affected / exposed	1 / 28 (3.57%)	0 / 30 (0.00%)	
occurrences (all)	1	1	
Gastrointestinal disorders			

PONV subjects affected / exposed occurrences (all)	1 / 28 (3.57%) 4	3 / 30 (10.00%) 4	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
10 November 2018	We found out that our patients are being followed-up by the gynecologists every 3 months for approximately 1 year, so we decided that we design a questionnaire to ask for patient satisfaction and pain. By extending the observation period, we had to make a substantial amendment.

Notes:

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/34872040