Clinical trial results:
Impact of the serratus plane block in pain and in the use of opioids in breast surgery

Summary

EudraCT number	2015-005773-21
Trial protocol	ES
Global end of trial date	06 November 2017

Results information

Result version number	v1 (current)
This version publication date	10 February 2022
First version publication date	10 February 2022
Summary attachment (see zip file)	Article IBMS-SPB (ARTICULO_mazzinari2019.pdf)

Trial information

Trial identification

Sponsor protocol code	IBMS-SPB

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Instituto de Investigación Sanitaria La Fe de Valencia
Sponsor organisation address	Avenida Fernando Abril Martorell, Torre 106 A 7planta, Valencia, Spain, 46026
Public contact	UREC, INSTITUTO DE INVESTIGACIÓN SANITARIA LA FE, 34 961246611, investigacion_clinica@iislafe.es
Scientific contact	UREC, INSTITUTO DE INVESTIGACIÓN SANITARIA LA FE, 34 961246611, investigacion_clinica@iislafe.es

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	22 February 2018
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	06 November 2017
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To evaluate the use of opioid drugs during breast oncologic surgery and to analyze the efficacy of serratus plane block as a opiates-saving method.

Protection of trial subjects:

The reference study was conducted in Spain under the legal framework of Royal Decree 1090/2015. It has been performed in accordance with the Declaration of Helsinki on Ethical Principles for Medical Research Involving Human Subjects, adopted by the General Assembly of the World Medical Association (1996). In addition, the study has been conducted in accordance with the protocol, good clinical practice (GCP) in accordance with the guidelines of the international conference on harmonization (ICH) and regulatory requirements for participating institutions.

An appropriately performed informed consent has been used, in compliance with GCP according to ICH guidelines and approved by the CEIm of the Hospital Universitario y Politécnico La Fe. Prior to inclusion of subjects in the study, a copy of the CEIm-approved informed consent has been reviewed with the prospective participant, signed and dated. The investigator has provided a copy of each subject's signed informed consent form and has retained a copy in the subject's study file.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	13 June 2016
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	Spain: 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)	60
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Patients undergoing oncologic and/or reconstructive breast surgery whose pathology and surgical intervention requires a hospital stay of at least 24 hours.

Pre-assignment

Screening details:

>18 years old, ASA classification (I-III), patients undergoing breast oncological surgery and/or breast reconstructive whose surgical proceadure needs a postoperative income of, at least, 24 hours.

Pre-assignment period milestones

Number of subjects started	60
Number of subjects completed	60

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Control group

Arm description:

With no block of serratum muscle

Arm type	Active comparator
Investigational medicinal product name	No Blocking of Serratum Muscle
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Not assigned
Routes of administration	Not mentioned

Dosage and administration details:

No Blocking of Serratum Muscle

Arm title	Experimental Group

Arm description:

With block of the Serratum muscle

Arm type	Experimental
Investigational medicinal product name	Blockage of Serrartum muscle
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Not assigned
Routes of administration	Not mentioned

Dosage and administration details:

Analgesic block of the serratus muscle is performed by means of a high-frequency flat probe ultrasound.

Number of subjects in period 1	Control group	Experimental Group
Started	30	30
Completed	30	28
Not completed	0	2
Lost to follow-up	-	2

Baseline characteristics

Reporting groups	
Reporting group title	Analysis

Reporting group description: -

Reporting group values	Analysis	Total	
Number of subjects	60	60	
Age categorical Units: Subjects			
Adults (18-64 years)	60	60	
Gender categorical Units: Subjects			
Female	60	60	
Male	0	0	

End points

End points reporting groups	
Reporting group title	Control group
Reporting group description: With no block of serratum muscle	
Reporting group title	Experimental Group
Reporting group description: With block of the Serratum muscle	

Primary: Opioid consumption	
End point title	Opioid consumption
End point description:	
End point type	Primary
End point timeframe: 24 hours	

End point values	Control group	Experimental Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	30	28		
Units: mg				
median (confidence interval 95%)	30 (21 to 41)	18.5 (14.5 to 29)		

Statistical analyses

Statistical analysis title	T-Test
Comparison groups	Control group v Experimental Group
Number of subjects included in analysis	58
Analysis specification	Pre-specified
Analysis type	superiority
Method	t-test, 2-sided
Parameter estimate	Median difference (final values)
Point estimate	9
Confidence interval	
level	95 %
sides	2-sided
lower limit	4
upper limit	14.5
Variability estimate	Standard deviation

Adverse events

Adverse events information[1]

Timeframe for reporting adverse events:

All events that meet the definition of an AE and occur within the period from when the patient signs the informed consent form and until the end of the post-treatment follow-up period required by the protocol should be recorded.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	24.1

Reporting groups

Reporting group title	Adverse Events

Reporting group description:

No adverse events have been recorded in the final Report

Serious adverse events	Adverse Events		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 60 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		

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

Non-serious adverse events	Adverse Events		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 60 (0.00%)		

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: No serious Adverse Events have been recorded in the Final Result 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

Online references

http://www.ncbi.nlm.nih.gov/pubmed/30640653