Clinical trial results:
Effectiveness of Added blocking of radial and median nerves with levobupivacaine in the control of postoperative pain in the rhizarthrosis ambulatory surgery

Summary

EudraCT number	2011-001340-29
Trial protocol	ES
Global end of trial date	03 February 2015

Results information

Result version number	v1 (current)
This version publication date	23 July 2021
First version publication date	23 July 2021

Trial information

Trial identification

Sponsor protocol code	IIBSP-LEV-2011-21

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01597479
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Institut de Recerca de l'Hospital de la Santa Creu i Sant Pau - IIB Sant Pau
Sponsor organisation address	Sant Quintí 77-79, Barcelona, Spain, 08041
Public contact	UICEC Sant Pau, Institut de Recerca de l'Hospital de la Santa Creu i Sant Pau, 34 935537636, uicec@santpau.cat
Scientific contact	UICEC Sant Pau, Institut de Recerca de l'Hospital de la Santa Creu i Sant Pau - IIB Sant Pau, 34 935537636, uicec@santpau.cat

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	21 March 2016
Is this the analysis of the primary completion data?	Yes
Primary completion date	01 April 2014
Global end of trial reached?	Yes
Global end of trial date	03 February 2015
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To study the efficacy of peripheral block of the radial and median nerves to control pain after outpatient surgery for rhizarthrosis at the time of maximum intensity, that is, in the first 24-48 hours.

Protection of trial subjects:

This trial was conducted in compliance with the principles laid down the Declaration of Helsinki and all applicable EU and national laws.
In addition, it adheres to the principles expressed in ICH-GCP (International Conference on Harmonization - Good Clinical Practice) and the requirements of the EU and National Data Protection Regulation.
Study protocol including consent documents were approved in advance by the leading Ethic Committee, by competent authorities and any other regulatory bodies (as specified by national regulations).
Participants in the clinical trial were adequately informed prior to their inclusion. In particular, all patients were informed about the voluntary nature of his/her participation, confidentiality and protection of his/her data, potential risks and benefits of participation, insurance coverage and the possibility of withdrawal at any time. The principle of patient autonomy was clearly enforced. Freely given informed consent was obtained from and documented in writing, signed and dated personally by each patient (or by an individual or juridical or other body authorized under applicable law to consent on behalf of a prospective subject) before he/she is inclusion in any study or project.
The protection of human subjects is also promoted by adequate monitoring of drug/treatment safety.

Background therapy: -	
Evidence for comparator: -	
Actual start date of recruitment	01 February 2010
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: 52
Worldwide total number of subjects	52
EEA total number of subjects	52

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)	0
From 65 to 84 years	52
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

We enrolled consecutive adult ASA I-III patients undergoing elective ambulatory trapeziectomy from February 2012 to april 2014.

Pre-assignment

Screening details:

-Men or women over 18 years of age.
-Outpatient surgery for rhizarthrosis.
-Free acceptance to participate in the study, with consent informed signed by the patient, guardian or responsible family member.

Pre-assignment period milestones

Number of subjects started	52
Number of subjects completed	52

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	ARM H

Arm description: -

Arm type	No intervention

No investigational medicinal product assigned in this arm

Arm title	ARM R

Arm description: -

Arm type	Experimental
Investigational medicinal product name	Levobupivacaína
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Injection

Dosage and administration details:

Infiltration and nerve block with 5 mL 0.125% levobupivacaine

Number of subjects in period 1	ARM H	ARM R
Started	26	26
Completed	26	26

Period 2	
Period 2 title	Visit 2
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms	
Are arms mutually exclusive?	Yes
Arm title	ARM H
Arm description: -	
Arm type	No intervention
No investigational medicinal product assigned in this arm	
Arm title	ARM R
Arm description: -	
Arm type	Experimental
Investigational medicinal product name	Levobupivacaína
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Injection

Dosage and administration details:

Infiltration and nerve block with 5 mL 0.125% levobupivacaine

Number of subjects in period 2	ARM H	ARM R
Started	26	26
Completed	26	26

Baseline characteristics

Reporting groups	
Reporting group title	ARM H
Reporting group description: -	
Reporting group title	ARM R
Reporting group description: -	

Reporting group values	ARM H	ARM R	Total
Number of subjects	26	26	52
Age categorical Units: Subjects			
Adults (18-64 years)	0	0	0
From 65-84 years	26	26	52
85 years and over	0	0	0
Gender categorical Units: Subjects			
Female	13	13	26
Male	13	13	26

End points

End points reporting groups	
Reporting group title	ARM H
Reporting group description: -	
Reporting group title	ARM R
Reporting group description: -	
Reporting group title	ARM H
Reporting group description: -	
Reporting group title	ARM R
Reporting group description: -	

Primary: Pain intensity at 24 and 48 hours after trapeziectomy	
End point title	Pain intensity at 24 and 48 hours after trapeziectomy
End point description:	
End point type	Primary
End point timeframe:	
24 and 48 post trapeziectomy	

End point values	ARM H	ARM R	ARM H	ARM R
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	26	26	26	26
Units: 1-10				
number (not applicable)	26	26	26	26

Statistical analyses

Statistical analysis title	x2
Comparison groups	ARM H v ARM R v ARM H v ARM R
Number of subjects included in analysis	104
Analysis specification	Post-hoc
Analysis type	equivalence
P-value	< 0.05
Method	Chi-squared
Parameter estimate	Median difference (final values)
Confidence interval	
level	95 %
sides	1-sided
lower limit	0
upper limit	10
Variability estimate	Standard deviation

Adverse events

Adverse events information	
Timeframe for reporting adverse events:	
48 hours	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	17

Reporting groups	
Reporting group title	ARM H
Reporting group description:	
Received an axillary brachial plexus block before surgery	
Reporting group title	ARM R
Reporting group description:	
Patients received an axillary brachial plexus block before surgery. In the postanesthesia care unit , patients in this group received a concomitant block of the median and radial nerves at the elbow	

Serious adverse events	ARM H	ARM R	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 26 (0.00%)	0 / 26 (0.00%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events			

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

Non-serious adverse events	ARM H	ARM R	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	4 / 26 (15.38%)	1 / 26 (3.85%)	
Gastrointestinal disorders			
Nausea			
subjects affected / exposed	4 / 26 (15.38%)	1 / 26 (3.85%)	
occurrences (all)	4	1	

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/29405670