Clinical trial results:
Intravenous regional anesthesia versus axillar block for hand surgery in day-care hospitall: A prospective, randomised, comparative trial

Summary

EudraCT number	2016-002325-11
Trial protocol	BE
Global end of trial date	07 November 2017

Results information

Result version number	v1 (current)
This version publication date	30 December 2019
First version publication date	30 December 2019

Trial information

Trial identification

Sponsor protocol code	AT052016

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	University Hospitals Leuven
Sponsor organisation address	Herestraat 49, Leuven, Belgium,
Public contact	Anesthesie Research, University Hospital Leuven, christel.huygens@uzleuven.be
Scientific contact	Anesthesie Research, University Hospital Leuven, christel.huygens@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	08 November 2018
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	07 November 2017
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

No difference in patient satisfaction scores for both groups

Protection of trial subjects:

All patients received prophylactic pain medication (paracetamol, ketorolac) according to the protocol.
Pain scores (intra-operative and post-operative) were monitored frequently.
Other adverse events (e.g. postoperative nausea and vomiting, neurological symptoms) were evaluated until dicharge and one day after surgery (by telephone).

All measures to prevent discomfort and pain were described in detail in the protocol.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 September 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	Belgium: 120
Worldwide total number of subjects	120
EEA total number of subjects	120

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)	95
From 65 to 84 years	24
85 years and over	1

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

In this prospective, randomized controlled trial, we enrolled 120 patients undergoing carpal tunnel release, resection of a wrist cyst or Dupuytren release (with a maximum of 2 strands) under RA in an ambulatory setting.
We included only patients with an American Society of Anesthesiologists physical status I - III, ≥ 18 years of age, scheduled f

Pre-assignment period milestones

Number of subjects started	120
Number of subjects completed	120

Period 1

Period 1 title	overall trial (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Intravenous regional anaesthesia

Arm description: -

Arm type	Experimental
Investigational medicinal product name	Lidocain
Investigational medicinal product code	
Other name	IVRA
Pharmaceutical forms	Solution for injection/infusion
Routes of administration	Intravenous use

Dosage and administration details:

300 mg
total volume of 40 mL

In patients allocated to the IVRA-group, all anesthetic measures were performed in the operation room (OR). A cannula (22G, BD Insyte-W; Becton,Dickinson Benelux N.V., Erembodegem, Belgium) was inserted into a vein on the back of the hand at the operative side. A tourniquet with a double cuff was attached around the upper arm. Then, an Esmarch was wrapped tightly while lifting the arm, thereby exsanguinating the arm.16 Subsequently, the proximal cuff of the tourniquet was insufflated to 250 mmHg, and the Esmarch was removed. 300 mg of lidocaine in a total volume of 40 mL was injected slowly through the intravenous catheter, which was removed afterwards.

Arm title	Axillary block

Arm description: -

Arm type	Experimental
Investigational medicinal product name	mepivacaine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Infiltration

Dosage and administration details:

280 mg (mepivacain 1%)
total volume 28 ml
In patients allocated to receive an axillary block, regional anesthesia was performed in the preoperative preparation and block room. The arm to be operated was abducted at 90° and the forearm flexed to a 90° angle. With the use of ultrasound, the following 4 nerves were identified as hyperechoic structures: the median, ulnar and radial nerve surrounding the axillary artery and the musculocutaneous nerve in the fascial layers between the biceps and coracobrachialis muscles. Local anesthesia of the puncture site was achieved with a subcutaneous injection of 2 mL lidocaine 1%. The needle (Stimuplex® Ultra 360 0.71x 50mm; G 22; B. Braun® Medical Inc., Melsungen, Hessen, Germany) was inserted in the axilla under ultrasound guidance with the probe in plane.14 Both ultrasound and neuro-stimulation were used to detect the nerves and to decrease the risk of intra-neural puncture/injection. After the initial motor response of the median nerve was obta

Number of subjects in period 1	Intravenous regional anaesthesia	Axillary block
Started	60	60
Completed	60	60

Baseline characteristics

Reporting groups	
Reporting group title	Intravenous regional anaesthesia
Reporting group description: -	
Reporting group title	Axillary block
Reporting group description: -	

Reporting group values	Intravenous regional anaesthesia	Axillary block	Total
Number of subjects	60	60	120
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			
arithmetic mean	53	50	
standard deviation	± 16	± 15	-
Gender categorical Units: Subjects			
Female	31	32	63
Male	29	28	57
ASA Units: Subjects			
ASA 1	24	32	56
ASA 2	26	24	50
ASA 3	10	4	14
weight Units: kilogram(s)			
arithmetic mean	75	76	
standard deviation	± 15	± 15	-
height Units: centimeter			
arithmetic mean	170	171	
standard deviation	± 8	± 10	-

End points

End points reporting groups

Reporting group title	Intravenous regional anaesthesia
Reporting group description: -	
Reporting group title	Axillary block
Reporting group description: -	

Primary: Patient satisfaction

End point title	Patient satisfaction

End point description:

Patient satisfaction was evaluated using the "Evaluation du Vécu de l' Anesthésie LocoRegional" (EVAN-LR) questionnaire which was specially developed for the evaluation of patient satisfaction after RA.18 (Addendum 1) In addition, patients were asked if they would choose the same anesthesia technique in the future. All questions were completed just before discharge, except for those items, which are home related (question 12-13-14). These questions were asked during a postoperative phone call interview at day 1 during which patients were also asked for the occurrence of adverse events and postoperative pain.

End point type	Primary

End point timeframe:

Day of surgery and day after surgery (see description).

End point values	Intravenous regional anaesthesia	Axillary block		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	60	60		
Units: score				
median (inter-quartile range (Q1-Q3))	92 (87 to 96)	97 (87 to 97)		

Statistical analyses

Statistical analysis title	patient satisfaction
Comparison groups	Intravenous regional anaesthesia v Axillary block
Number of subjects included in analysis	120
Analysis specification	Pre-specified
Analysis type	non-inferiority
P-value	< 0.05
Method	Wilcoxon (Mann-Whitney)

Secondary: NRS for pain

End point title	NRS for pain

End point description:

End point type	Secondary
End point timeframe: Intra-oparative (day of surgery)	

End point values	Intravenous regional anaesthesia	Axillary block		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	60	60		
Units: score				
median (inter-quartile range (Q1-Q3))	0 (0 to 2)	0 (0 to 0)		

Statistical analyses

Statistical analysis title	NRS for pain intra-operatively
Comparison groups	Intravenous regional anaesthesia v Axillary block
Number of subjects included in analysis	120
Analysis specification	Pre-specified
Analysis type	equivalence
P-value	< 0.001
Method	Wilcoxon (Mann-Whitney)

Secondary: VAS pain score postopartively	
End point title	VAS pain score postopartively
End point description: VAS score for pain post-operatively	
End point type	Secondary
End point timeframe: Day of surgery	

End point values	Intravenous regional anaesthesia	Axillary block		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	60	60		
Units: score				
median (inter-quartile range (Q1-Q3))	0.79 (0 to 1.76)	0 (0 to 0.25)		

Statistical analyses

Statistical analysis title	VAS score postoperatively
Comparison groups	Axillary block v Intravenous regional anaesthesia
Number of subjects included in analysis	120
Analysis specification	Pre-specified
Analysis type	equivalence
P-value	< 0.001
Method	Wilcoxon (Mann-Whitney)

Secondary: PONV medication

End point title	PONV medication
End point description:	
Need for treatment for postoperative nausea and vomiting (day of surgery)	
End point type	Secondary
End point timeframe:	
Until discharge	

End point values	Intravenous regional anaesthesia	Axillary block		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	60	60		
Units: number				
Yes	1	1		
No	59	59		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

During surgery
Postoperatively (day of surgery until discharge DSU)
Day 1 after surgery (by telephone conversation)

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	21.1

Reporting groups

Reporting group title	Intravenous regional anaesthesia
Reporting group description: -	
Reporting group title	Axillary block

Reporting group description: -

Serious adverse events	Intravenous regional anaesthesia	Axillary block	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 60 (0.00%)	0 / 60 (0.00%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0		

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

Non-serious adverse events	Intravenous regional anaesthesia	Axillary block	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	7 / 60 (11.67%)	8 / 60 (13.33%)	
Nervous system disorders			
numbness of hand/fingers			
subjects affected / exposed	7 / 60 (11.67%)	3 / 60 (5.00%)	
occurrences (all)	10	10	
Ear and labyrinth disorders			
Tinnitus			
subjects affected / exposed	2 / 60 (3.33%)	0 / 60 (0.00%)	
occurrences (all)	2	2	

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/30035357