Clinical trial results:
Analgésie post-césarienne: intérêt de l'injection sous-aponévrotique d'anesthésique local par cathéter multiperforé, par rapport à la morphine intrathécale.

Summary

EudraCT number	2012-000647-27
Trial protocol	BE
Global end of trial date	12 December 2014

Results information

Result version number	v1 (current)
This version publication date	30 July 2021
First version publication date	30 July 2021

Trial information

Trial identification

Sponsor protocol code	CHU-930106

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02264821
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Chu Brugmann
Sponsor organisation address	4 Place A. Van Gehuchten , Brussels, Belgium, 1020
Public contact	Philippe Van der Linden , CHU Brugmann, 32 024772330, Philippe.VANDERLINDEN@chu-brugmann.be
Scientific contact	Philippe Van der Linden , CHU Brugmann, 32 024772330, Philippe.VANDERLINDEN@chu-brugmann.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	12 December 2014
Is this the analysis of the primary completion data?	Yes
Primary completion date	28 May 2014
Global end of trial reached?	Yes
Global end of trial date	12 December 2014
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Comparison of the duration of postoperative analgesia and side effects of two perioperative analgesia techniques: either the infusion of local anesthetic via a multiperforated catheter or the addition of intrathecal morphine compared to a placebo in elective cesarean sections under spinal anesthesia.

Protection of trial subjects:

According to the standard of care

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	05 September 2012
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: 182
Worldwide total number of subjects	182
EEA total number of subjects	182

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)	182
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

478 patients were assessed for eligibility. 192 patients were randomized. 182 patients were analyzed (due to pump technical problems (5), catheter misplacement (1), surgical reason to not insert catheter (2), midline incision (1), vaginal delivery (1)).

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, Subject, Carer, Assessor

Arms

Are arms mutually exclusive?	Yes
Arm title	Control group

Arm description:

Bupivacaine spine anesthesia 0.5 HB 10mg + Sufenta 5µg + 0.1 ml of placebo and placement of a multiperforated catheter with an elastomeric infusor pump containing 300 ml of placebo delivering 10ml / h for 30h.

Arm type	Active comparator
Investigational medicinal product name	Bupivacaine 0.5% 10mg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intrathecal use

Dosage and administration details:

Bupivacaine 0.5% 10mg, intrathecal use, solution for injection

Investigational medicinal product name	Sufentanyl 5µg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intrathecal use

Dosage and administration details:

Sufentanyl 5µg intrathecal injection

Arm title	Group rachi morphine

Arm description:

Bupivacaine spinal anesthesia 0.5% HB 10mg + Sufenta 5µg + 0.1 mg of morphine (0.1 ml) and placement of a multiperforated catheter with an elastomeric infusor pump containing 300 ml of placebo delivering 10ml / h for 30h

Arm type	Experimental
Investigational medicinal product name	Bupivacaine 0.5% 10mg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intrathecal use

Dosage and administration details:

Bupivacaine 0.5% 10mg, intrathecal use, solution for injection

Investigational medicinal product name	Sufentanil 5µg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intrathecal use

Dosage and administration details:

Sufentanil 5µg intrathecal injection

Investigational medicinal product name	Morphine 100µg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intrathecal use

Dosage and administration details:

Morphine 100µg, intrathecal injection

Arm title	Group catheter

Arm description:

Bupivacaine spinal anesthesia 0.5% HB 10mg + Sufenta 5µg + 0.1 ml of placebo and placement of a multiperforated catheter with an elastomeric infuser pump containing 300ml of ropivacaine 2mg / ml delivering 10ml / h for 30h

Arm type	Experimental
Investigational medicinal product name	Bupivacaine 0.5% 10mg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intrathecal use

Dosage and administration details:

Bupivacaine 0.5% 10mg, intrathecal use, solution for injection

Investigational medicinal product name	Sufentanyl 5µg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intrathecal use

Dosage and administration details:

Sufentanyl 5µg intrathecal injection

Investigational medicinal product name	Ropivacaine 0.2%
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection/infusion
Routes of administration	Subcutaneous use

Dosage and administration details:

Ropivacaine 0.2% 10ml/h during 30h

Number of subjects in period 1	Control group	Group rachi morphine	Group catheter
Started	58	61	63
Completed	58	61	63

Baseline characteristics

Reporting groups	
Reporting group title	Control group
Reporting group description:	
Bupivacaine spine anesthesia 0.5 HB 10mg + Sufenta 5µg + 0.1 ml of placebo and placement of a multiperforated catheter with an elastomeric infusor pump containing 300 ml of placebo delivering 10ml / h for 30h.	
Reporting group title	Group rachi morphine
Reporting group description:	
Bupivacaine spinal anesthesia 0.5% HB 10mg + Sufenta 5µg + 0.1 mg of morphine (0.1 ml) and placement of a multiperforated catheter with an elastomeric infusor pump containing 300 ml of placebo delivering 10ml / h for 30h	
Reporting group title	Group catheter
Reporting group description:	
Bupivacaine spinal anesthesia 0.5% HB 10mg + Sufenta 5µg + 0.1 ml of placebo and placement of a multiperforated catheter with an elastomeric infuser pump containing 300ml of ropivacaine 2mg / ml delivering 10ml / h for 30h	

Reporting group values	Control group	Group rachi morphine	Group catheter
Number of subjects	58	61	63
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)	58	61	63
From 65-84 years	0	0	0
85 years and over	0	0	0
Gender categorical Units: Subjects			
Female	58	61	63
Male	0	0	0

Reporting group values	Total		
Number of subjects	182		
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)	182		

From 65-84 years	0		
85 years and over	0		

Gender categorical Units: Subjects			
Female	182		
Male	0		

End points

End points reporting groups

Reporting group title	Control group
Reporting group description:	
Bupivacaine spine anesthesia 0.5 HB 10mg + Sufenta 5µg + 0.1 ml of placebo and placement of a multiperforated catheter with an elastomeric infusor pump containing 300 ml of placebo delivering 10ml / h for 30h.	
Reporting group title	Group rachi morphine
Reporting group description:	
Bupivacaine spinal anesthesia 0.5% HB 10mg + Sufenta 5µg + 0.1 mg of morphine (0.1 ml) and placement of a multiperforated catheter with an elastomeric infusor pump containing 300 ml of placebo delivering 10ml / h for 30h	
Reporting group title	Group catheter
Reporting group description:	
Bupivacaine spinal anesthesia 0.5% HB 10mg + Sufenta 5µg + 0.1 ml of placebo and placement of a multiperforated catheter with an elastomeric infuser pump containing 300ml of ropivacaine 2mg / ml delivering 10ml / h for 30h	

Primary: Duration of effective analgesia

End point title	Duration of effective analgesia
End point description:	
End point type	Primary
End point timeframe:	
Duration of effective analgesia defined as the time between the completion of spinal analgesia and the first morphine request by the patient.	

End point values	Control group	Group rachi morphine	Group catheter	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	58	61	63	
Units: minutes	247	380	351	

Statistical analyses

Statistical analysis title	Kruskal-wallis Rank test
Comparison groups	Control group v Group rachi morphine v Group catheter
Number of subjects included in analysis	182
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.05
Method	Kruskal-wallis

Secondary: Morphine Consumption

End point title	Morphine Consumption

End point description:

End point type	Secondary

End point timeframe:

During the first 30h following spinal anesthesia

End point values	Control group	Group rachi morphine	Group catheter	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	58	61	63	
Units: mg	21	10	8	

Statistical analyses

Statistical analysis title	Kruskal-wallis

Statistical analysis description:

Kruskal-wallis followed by Tuckey's multiple comparisons test

Comparison groups	Control group v Group rachi morphine v Group catheter
Number of subjects included in analysis	182
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.05
Method	Kruskal-wallis

Adverse events

Adverse events information	
Timeframe for reporting adverse events:	
Entire clinical trial	
Assessment type	Systematic

Dictionary used	
Dictionary name	Clinical practice
Dictionary version	N/A

Reporting groups	
Reporting group title	Control group
Reporting group description:	
Bupivacaine spine anesthesia 0.5 HB 10mg + Sufenta 5µg + 0.1 ml of placebo and placement of a multiperforated catheter with an elastomeric infusor pump containing 300 ml of placebo delivering 10ml / h for 30h.	
Reporting group title	Group rachi morphine
Reporting group description:	
Bupivacaine spinal anesthesia 0.5% HB 10mg + Sufenta 5µg + 0.1 mg of morphine (0.1 ml) and placement of a multiperforated catheter with an elastomeric infusor pump containing 300 ml of placebo delivering 10ml / h for 30h	
Reporting group title	Group catheter
Reporting group description:	
Bupivacaine spinal anesthesia 0.5% HB 10mg + Sufenta 5µg + 0.1 ml of placebo and placement of a multiperforated catheter with an elastomeric infuser pump containing 300ml of ropivacaine 2mg / ml delivering 10ml / h for 30h	

Serious adverse events	Control group	Group rachi morphine	Group catheter
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 58 (0.00%)	0 / 61 (0.00%)	0 / 63 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0

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

Non-serious adverse events	Control group	Group rachi morphine	Group catheter
Total subjects affected by non-serious adverse events			
subjects affected / exposed	30 / 58 (51.72%)	35 / 61 (57.38%)	31 / 63 (49.21%)
Cardiac disorders			
Hypotension			
subjects affected / exposed	30 / 58 (51.72%)	23 / 61 (37.70%)	22 / 63 (34.92%)
occurrences (all)	1	1	1
Gastrointestinal disorders			

Nausea			
subjects affected / exposed	9 / 58 (15.52%)	18 / 61 (29.51%)	10 / 63 (15.87%)
occurrences (all)	1	1	1
Skin and subcutaneous tissue disorders			
Pruritus			
subjects affected / exposed	21 / 58 (36.21%)	35 / 61 (57.38%)	31 / 63 (49.21%)
occurrences (all)	1	1	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/28368941