Clinical trial results:
Randomised comparative trial of Bupivacaine and 2-Chloroprocaine by caesarean section.

Summary

EudraCT number	2013-002815-88
Trial protocol	BE
Global end of trial date	26 March 2014

Results information

Result version number	v1 (current)
This version publication date	30 September 2020
First version publication date	30 September 2020
Summary attachment (see zip file)	Article (Maes_et_al-2016-Acta_Anaesthesiologica_Scandinavica.pdf)

Trial information

Trial identification

Sponsor protocol code	BUPCHLOR1

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	UZ Brussel
Sponsor organisation address	Laarbeeklaan 101, Jette, Belgium, 1090
Public contact	Department of Anesthesiology, UZ Brussel, 24763618 24763618, luc.puis@uzbrussel.be
Scientific contact	Department of Anesthesiology, UZ Brussel, 24763618 24763618, luc.puis@uzbrussel.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	26 March 2014
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	26 March 2014
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The goal of this trial is to investigate the efficacy of the IMP during c-section with and without the use of Sufenta: As well as start of action, duration of action, the degree of motor and sensory block as well as the hight of the block itselfs will be investigated.

Protection of trial subjects:

If patients of a certain group was in distress there was a rescue dose available.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	31 July 2013
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: 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: -

Pre-assignment

Screening details:

Inclusion: in-term (≥ 37 weeks),ASA I,II, planned CS,uncomplicated, singleton pregnancy, age 18-40 years. Exclusion: ASA III,IV, urgent/emergent CS, twin/multiple pregnancy, gestational age<37 weeks, BMI > 35, maternal height < 150 cm, foetus with known or suggested congenital malformations, known allergy for anaesthetics and (pre)eclampsia.

Period 1

Period 1 title	Overall Trial (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Single blind
Roles blinded	Subject

Blinding implementation details:

Anesthesiologist receives an envelop to know which group the patient will be in. Patient is not informed of which medication they will receive.

Arms

Are arms mutually exclusive?	Yes
Arm title	Group C

Arm description:

Patients received 2-chloroprocaine.

Arm type	Experimental
Investigational medicinal product name	Chloroprocaine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for injection/infusion
Routes of administration	Epidural use

Dosage and administration details:

40 mg 2-chloroprocaine spinal-epidural

Arm title	Group C+S

Arm description:

Patients receive 2-chloroprocaine and sufentanil

Arm type	Experimental
Investigational medicinal product name	Chloroprocaine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for injection/infusion
Routes of administration	Epidural use

Dosage and administration details:

40 mg 2-chloroprocaine spinal-epidural

Investigational medicinal product name	Sufentanil
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for injection/infusion
Routes of administration	Epidural use

Dosage and administration details: 1 mcg sufentanil spinal-epidural

Arm title	Group B+S
Arm description: Hyperbaric bupivacaine (9 mg) with sufentanil (1 mcg)	
Arm type	Active comparator
Investigational medicinal product name	Sufentanil
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for injection/infusion
Routes of administration	Epidural use
Dosage and administration details: 1 mcg sufentanil spinal-epidural	
Investigational medicinal product name	Bupivacaine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for injection/infusion
Routes of administration	Epidural use
Dosage and administration details: Hyperbaric bupivacaine 9 mg and 1 mcg of sufentanil were spinal-epidural given to patients.	

Number of subjects in period 1	Group C	Group C+S	Group B+S
Started	20	20	20
Completed	20	20	20

Baseline characteristics

Reporting groups	
Reporting group title	Overall Trial

Reporting group description: -

Reporting group values	Overall Trial	Total	
Number of subjects	60	60	
Age categorical			
Age 18-40			
Units: Subjects			
In utero	0	0	
Preterm newborn infants (gestational age < 37 wks)	0	0	
Newborns (0-27 days)	0	0	
Infants and toddlers (28 days-23 months)	0	0	
Children (2-11 years)	0	0	
Adolescents (12-17 years)	0	0	
Adults (18-64 years)	60	60	
From 65-84 years	0	0	
85 years and over	0	0	
Gender categorical			
Female			
Units: Subjects			
Female	60	60	
Male	0	0	

End points

End points reporting groups	
Reporting group title	Group C
Reporting group description:	
Patients received 2-chloroprocaine.	
Reporting group title	Group C+S
Reporting group description:	
Patients receive 2-chloroprocaine and sufentanil	
Reporting group title	Group B+S
Reporting group description:	
Hyperbaric bupivacaine (9 mg) with sufentanil (1 mcg)	

Primary: Time to motor block	
End point title	Time to motor block
End point description:	

End point type	Primary
End point timeframe:	
Time in minutes starting from IMP injection to motor block.	

End point values	Group C	Group C+S	Group B+S	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	20	20	20	
Units: minutes				
number (not applicable)	20	20	20	

Statistical analyses

Statistical analysis title	Mann-Whitney U test
Comparison groups	Group C v Group C+S v Group B+S
Number of subjects included in analysis	60
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.05
Method	Wilcoxon (Mann-Whitney)

Statistical analysis title	t-test
Comparison groups	Group C v Group C+S v Group B+S

Number of subjects included in analysis	60
Analysis specification	Pre-specified
Analysis type	equivalence
P-value	< 0.05
Method	t-test, 1-sided

Statistical analysis title	Fischer
Comparison groups	Group C v Group C+S v Group B+S
Number of subjects included in analysis	60
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.05
Method	Fisher exact

Secondary: Time to motor block resolution	
End point title	Time to motor block resolution
End point description:	
How long does it take for the patients to have full motor recovery after the caesarean.	
End point type	Secondary
End point timeframe:	
Time after surgery in minutes.	

End point values	Group C	Group C+S	Group B+S	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	20	20	20	
Units: minutes				
number (not applicable)	20	20	20	

Statistical analyses

Statistical analysis title	Mann-Whitney U test
Comparison groups	Group C v Group C+S v Group B+S
Number of subjects included in analysis	60
Analysis specification	Pre-specified
Analysis type	other[1]
P-value	< 0.05
Method	Wilcoxon (Mann-Whitney)

Notes:

[1] - randomly selected values X and Y from two populations, the probability that X is greater than Y is equal to the probability that Y is greater than X.

Statistical analysis title	T-test between groups
Comparison groups	Group C v Group C+S v Group B+S
Number of subjects included in analysis	60
Analysis specification	Pre-specified
Analysis type	equivalence
P-value	< 0.05
Method	t-test, 1-sided
Parameter estimate	Mean difference (net)

Statistical analysis title	Fisher
Comparison groups	Group C v Group C+S v Group B+S
Number of subjects included in analysis	60
Analysis specification	Pre-specified
Analysis type	equivalence
P-value	< 0.05
Method	Fisher exact

Adverse events

Adverse events information[1]	
Timeframe for reporting adverse events:	
During the caesarean and 1 day postop.	
Adverse event reporting additional description:	
There were no Adverse Events reported.	
Assessment type	Systematic

Dictionary used	
Dictionary name	CTCAE
Dictionary version	4.0

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

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: There were no Adverse Events reported.

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