Clinical trial results:
Paracervical block (PCB) during II-trimester abortion – a randomized controlled trial

Summary

EudraCT number	2010-020780-21
Trial protocol	SE
Global end of trial date	30 April 2015

Results information

Result version number	v1 (current)
This version publication date	31 March 2021
First version publication date	31 March 2021

Trial information

Trial identification

Sponsor protocol code	W2010IM

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01617564
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Karolinska Institutet
Sponsor organisation address	17177, Stockholm, Sweden,
Public contact	Kristina Gemzell Danielsson, Karolinska Institutet, kristina.gemzell@ki.se
Scientific contact	Kristina Gemzell Danielsson, Karolinska Institutet, kristina.gemzell@ki.se

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	30 April 2015
Is this the analysis of the primary completion data?	Yes
Primary completion date	30 April 2015
Global end of trial reached?	Yes
Global end of trial date	30 April 2015
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Can the number of women who experience severe pain (VAS> 7) during induced abortion after 13 weeks of gestation, be reduced through the use of PCBs with Marcain ® as a method of pain relief during abortion?

Protection of trial subjects:

Participation was voluntary and written informed consent was obtained prior to participating in any study-related activity.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	29 May 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	Sweden: 102
Worldwide total number of subjects	102
EEA total number of subjects	102

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)	102
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Women were recruited from a gynaecological clinic in Sweden between during May 2012 until April 2015.

Pre-assignment

Screening details:

Women who were 18 years or older, gestational age from 13 weeks and being able to understand Swedish were screened for participation. 589 women had a second-trimester abortion during the time period, 276 of those women were informed and invited to participate in the study, and 113 women were recruited.

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	Subject, Investigator

Arms

Are arms mutually exclusive?	Yes
Arm title	Placebo

Arm description:

Participants received a PCB (Paracervical block) with 20 ml sodium chloride 9 mg/ml (Placebo).

Arm type	Placebo
Investigational medicinal product name	Sodium Chloride
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intracervical use

Dosage and administration details:

The PCB was administered as a 2–4 mm deep paracervical injection into the mucosa at two sites (2 and 8 o'clock), and was applied by using a Kobac's needle or an ordinary injection needle (0.8 × 80 mm)during a speculum examination. The procedure lasted for 5 min. The PCB was applied 1 h after the first dose of misoprostol.

Arm title	Bupivacaine

Arm description:

Participants received a PCB (Paracervical block) with 20 ml local anaesthesia (bupivacaine 2.5 mg/ml)

Arm type	Experimental
Investigational medicinal product name	Bupivacaine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intracervical use

Dosage and administration details:

The PCB was administered as a 2–4 mm deep paracervical injection into the mucosa at two sites (2 and 8 o'clock), and was applied by using a Kobac's needle or an ordinary injection needle (0.8 × 80 mm) during a speculum examination. The procedure lasted for 5 min. The PCB was applied 1 h after the first dose of misoprostol.

Number of subjects in period 1	Placebo	Bupivacaine
Started	50	52
Completed	50	52

Baseline characteristics

Reporting groups	
Reporting group title	Placebo
Reporting group description:	
Participants received a PCB (Paracervical block) with 20 ml sodium chloride 9 mg/ml (Placebo).	
Reporting group title	Bupivacaine
Reporting group description:	
Participants received a PCB (Paracervical block) with 20 ml local anaesthesia (bupivacaine 2.5 mg/ml)	

Reporting group values	Placebo	Bupivacaine	Total
Number of subjects	50	52	102
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)	0	0	0
From 65-84 years	0	0	0
85 years and over	0	0	0
<25	15	22	37
25-34	19	20	39
>=35	16	10	26
Gender categorical Units: Subjects			
Female	50	52	102
Male	0	0	0

End points

End points reporting groups	
Reporting group title	Placebo
Reporting group description:	
Participants received a PCB (Paracervical block) with 20 ml sodium chloride 9 mg/ml (Placebo).	
Reporting group title	Bupivacaine
Reporting group description:	
Participants received a PCB (Paracervical block) with 20 ml local anaesthesia (bupivacaine 2.5 mg/ml)	

Primary: Highest pain intensity	
End point title	Highest pain intensity
End point description:	
Can paracervical block (PCB) administered before the onset of pain decrease women's pain experience during secondtrimester medical termination of pregnancy (MToP)? Pain was measured by VAS (visual analogue scale) where VAS 7-10 = severe pain.	
End point type	Primary
End point timeframe:	
Pain was measured at misoprostol initiation (baseline) and repeated every 30 min until fetal expulsion. The primary outcome was at any time point.	

End point values	Placebo	Bupivacaine		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	50	52		
Units: VAS				
VAS 0-6	17	13		
VAS 7-10	32	39		

Statistical analyses

Statistical analysis title	Difference in highest pain intensity VAS 7-10
Comparison groups	Placebo v Bupivacaine
Number of subjects included in analysis	102
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.292
Method	Generalized estimating equations model
Parameter estimate	Risk ratio (RR)
Confidence interval	
level	95 %
sides	2-sided

Adverse events

Adverse events information	
Timeframe for reporting adverse events: Misoprostol initiation (baseline) and repeated every 30 min until fetal expulsion.	
Assessment type	Systematic

Dictionary used	
Dictionary name	ICD
Dictionary version	10

Reporting groups	
Reporting group title	Placebo
Reporting group description: Participants received a PCB (Paracervical block) with 20 ml sodium chloride 9 mg/ml (Placebo).	
Reporting group title	Bupivacaine
Reporting group description: Participants received a PCB (Paracervical block) with 20 ml local anaesthesia (bupivacaine 2.5 mg/ml)	

Serious adverse events	Placebo	Bupivacaine	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 50 (0.00%)	0 / 52 (0.00%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	

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

Non-serious adverse events	Placebo	Bupivacaine	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	14 / 50 (28.00%)	14 / 52 (26.92%)	
Cardiac disorders			
Dizziness			
subjects affected / exposed	3 / 50 (6.00%)	3 / 52 (5.77%)	
occurrences (all)	50	52	
General disorders and administration site conditions			
Sensory loss			
subjects affected / exposed	0 / 50 (0.00%)	1 / 52 (1.92%)	
occurrences (all)	50	52	
Headache			

subjects affected / exposed occurrences (all)	0 / 50 (0.00%) 50	1 / 52 (1.92%) 52	
Gastrointestinal disorders Nausea/vomiting subjects affected / exposed occurrences (all)	 8 / 50 (16.00%) 50	 8 / 52 (15.38%) 52	
Respiratory, thoracic and mediastinal disorders Shortness of breath subjects affected / exposed occurrences (all)	 1 / 50 (2.00%) 50	 0 / 52 (0.00%) 52	
Skin and subcutaneous tissue disorders Skin rush subjects affected / exposed occurrences (all)	 1 / 50 (2.00%) 50	 0 / 52 (0.00%) 52	
Musculoskeletal and connective tissue disorders Shivering subjects affected / exposed occurrences (all)	 2 / 50 (4.00%) 50	 2 / 52 (3.85%) 52	

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

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

Nearly 60% of the invited women did notwant to participate in the study (fear of needles and fear of receiving the placebo) therefore women who tolerate pain may have been overrepresented in the study population.

Notes:

Online references

http://www.ncbi.nlm.nih.gov/pubmed/26573530