



Clinical trial results: Comparison of the ED95 dose of 0.075% and 0.1% bupivacaine for labour analgesia in primigravida

Summary

EudraCT number	2010-020020-21
Trial protocol	GB
Global end of trial date	14 April 2016

Results information

Result version number	v1 (current)
This version publication date	11 April 2020
First version publication date	11 April 2020
Summary attachment (see zip file)	Trial Terminated before Recruiting Statement (Trial Terminated before recruiting any participants statement.docx)

Trial information

Trial identification

Sponsor protocol code	AN10/9307
-----------------------	-----------

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	University of Leeds
Sponsor organisation address	Worsley Building, Leeds, United Kingdom, LS2 9JT
Public contact	Dr Anurag Vats, University of Leeds, 0113 2060440, a.vats@nhs.net
Scientific contact	Dr Anurag Vats, University of Leeds, 0113 2060440, a.vats@nhs.net

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	14 April 2016
Is this the analysis of the primary completion data?	Yes
Primary completion date	14 April 2016
Global end of trial reached?	Yes
Global end of trial date	14 April 2016
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

What is the dose of bupivacaine 0.075% and bupivacaine 0.1% that has 95% chance of success for epidural pain relief, during early part of labour, for a woman having first child.

Protection of trial subjects:

All primigravida women admitted to the labour ward will be given patient information leaflet on arrival. When they will request epidural anaesthesia, the stage of labour will be identified by the obstetric registrar in collaboration with midwives on call. The time between arrival on the ward and request for epidural is very variable and from our experiences it ranges between 30 minutes to 8 hours. The primigravida woman who will be in early labour will be approached for consent and assenting patients will be randomised to receive either 0.075% or 0.1% bupivacaine using sealed envelope method. The randomisation will be done by an independent person not connected to the trial.

Background therapy:

Local anaesthetics can cause toxicity by an absolute overdose, intravenous injection or slow intravascular absorption from the site of injection. In most cases, rates of severe systemic toxicity (seizures with or without cardiac arrest) occur in the order of 1:1000 for peripheral nerve blocks¹ and 1:10,000 for epidurals²⁻³. The risk of toxicity when performing regional anaesthesia can be reduced significantly by injecting the optimal amount of local anaesthetic at the correct site.

Evidence for comparator:

Fentanyl is regularly added to the loading dose of the bupivacaine for labour analgesia as it has been conclusively shown to reduce the dose, autonomic and motor side effects of the local anaesthetics required. Epidural fentanyl (40 µg) has been proven to have a significant local anaesthetic-sparing effect when used with levo-bupivacaine for epidural analgesia in early labour^{16, 17}. It reduces the side effects associated with higher concentration of local anaesthetic agents

Actual start date of recruitment	30 January 2015
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	United Kingdom: 99999
Worldwide total number of subjects	99999
EEA total number of subjects	99999

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)	99999
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Pregnant women are admitted to the labour ward when they go into labour. Depending upon the patient, they might be either in early labour or late labour. The stage of labour is decided by the cervical dilatation and the frequency of uterine contractions. For our study, only primigravida woman in early labour will be recruited.

Pre-assignment

Screening details:

The primigravida woman who will be in early labour will be approached for consent and assenting patients will be randomised to receive either 0.075% or 0.1% bupivacaine using sealed envelope method.

Period 1

Period 1 title	Main Trial Period (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Monitor, Data analyst, Carer, Assessor

Arms

Are arms mutually exclusive?	No
Arm title	0.075% Bupivacaine

Arm description: -

Arm type	Experimental
Investigational medicinal product name	bupivacaine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Epidural use

Dosage and administration details:

The operator will inject the study drug in the epidural space as part of the standard care.

Arm title	0.1% bupivacaine
------------------	------------------

Arm description: -

Arm type	Experimental
Investigational medicinal product name	bupivacaine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Epidural use

Dosage and administration details:

The operator will inject the study drug in the epidural space as part of the standard care.

Number of subjects in period 1	0.075% Bupivacaine	0.1% bupivacaine
Started	99998	1
Completed	99998	1

Baseline characteristics

Reporting groups

Reporting group title	Main Trial Period
-----------------------	-------------------

Reporting group description: -

Reporting group values	Main Trial Period	Total	
Number of subjects	99999	99999	
Age categorical			
Units: Subjects			
Adults	99999	99999	
Gender categorical			
Units: Subjects			
Female	99999	99999	
Male	0	0	

End points

End points reporting groups

Reporting group title	0.075% Bupivacaine
Reporting group description: -	
Reporting group title	0.1% bupivacaine
Reporting group description: -	

Primary: Effective starting Dose of bupivacaine

End point title	Effective starting Dose of bupivacaine ^[1]
End point description:	

End point type	Primary
End point timeframe:	
Patients assessed at the time of labor, and followed up once discharged.	

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: No statistical analysis's were performed, as no data was collected from any participants.

End point values	0.075% Bupivacaine	0.1% bupivacaine		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0 ^[2]	0 ^[3]		
Units: mg				

Notes:

[2] - No Data was collected on any participants, as no patients were randomised onto the study

[3] - No Data was collected on any participants, as no patients were randomised onto the study

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information^[1]

Timeframe for reporting adverse events:

Adverse events will be picked up either by the Chief Investigator (CI), the Principal Investigator (PI) or the nursing staff on the wards or the GP following discharge. Adverse events occurring up to 24 hours following administration will be 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: No Adverse events were recorded on the study, as no data was collected from any participants.

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.

The trial was early terminated due to poor recruitment
--

Notes: