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A randomised comparison between 0.5% Levobupivacaine with a lidocaine/epinephrine /fentanyl mixture for epidural top up for emergency caesarean section after low dose epidural for labour

Submission date
28/09/2007

Recruitment status
No longer recruiting

Registration date
28/09/2007

Overall study status
Completed

Last Edited
25/04/2012

Condition category
Pregnancy and Childbirth

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0084182454

Study information

Scientific Title

Study objectives
In our Trust, we commonly give lidocaine/epinephrine/fentanyl mixture for epidural top up for all pregnant women having emergency caesarian section. It takes a few minutes to mix this drug mixture however, 0.5% Levobupicaine is being used in a few other Trusts because of less time needed to give the solution, less side effects and longer duration of action. As no study has compared these two solutions, we have decided to compare both the solutions and to see whether 0.5% Levobupivacaine is superior to Lidocaine/Epinephrine/Fentanyl mixture for this group of patients. The principal research question is whether the time taken from the start of epidural drug preparation, until readiness for the surgery, is faster with Levobupivacaine or with Lidocaine/Fentanyl/Epinephrine mixture.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Prospective randomised single blind study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Pregnancy and Childbirth: Caesarean section

Interventions
This study is a prospective randomised single blind study that compares two commonly used epidural top up mixtures. This study will be done in women's and children's hospital, HRI. During

one year period there would usually be at least 300 epidural top ups for emergency LSCS in our labour suite. We decided to have a sample size of 50 patients in each group and calculated the power analysis from previous studies with alpha and beta of 0.05 and 0.2 respectively, looking for a 20% difference in the supplementation (either extra supplement of study drug or conversion to general anaesthetics) as highly significant. All patients having an epidural sited for pain relief in labour, once pain free, will be approached, and be asked to give informed consent. Using sealed envelopes, computer generated numbers will direct the anaesthetists as to which solution to use should an emergency LSCS become necessary. Usual documentation will be supplemented with the study data sheet and the anaesthetists responsible for the case will be asked to record all the relevant data. These sheets will be marked with the patients unit number and trial number so that follow up is possible. The data will be stored on a computerised database according to trial number alone. for any individual patient the study will end on completion of the study questionnaire during the routine anaesthetic follow up at 24 - 28 hours post LSCS. Consent will be obtained from women who are pain free after having received an epidural for pain relief during labour. Should such a patient require an emergency LSCS, the anaesthetist will time themselves preparing the randomly allocated solution. A stop watch situated in a trolley will allow for accurate time measurements and cause of any delays eg locating keys/ODA etc will be noted. details of the woman's previous top ups will be recorded, as well as the anaesthetic/analgesic levels and the degree of motor block immediately prior to top up for LSCS.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Levobupivacaine, lidocaine/epinephrine/fentanyl

Primary outcome measure
The time from start of top up drug preparation until the patient is ready for surgery (block to T6).

Secondary outcome measures
Not provided at time of registration

Overall study start date
13/04/2006

Completion date
22/01/2007

Eligibility

Key inclusion criteria
1. Participants suitable for LSCS under epidural
2. Mother and baby not in any immediate danger
3. Singleton pregnancy

4. > 16 years of age
5. No contraindication for regional anaesthesia
6. ASA grade I and grade II

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
100

Key exclusion criteria
1. A failed block in this labour
2. Poorly functioning epidural in this labour
3. Significant hypertension with previous top-ups during this labour
4. Under 16 years of age
5. Ante partum haemorrhage/abruption
6. Prelapsed cord
7. Severe fetal distress
8. Multiple pregnancies
9. Hypertension complicating pregnancy requiring therapy

Date of first enrolment
13/04/2006

Date of final enrolment
22/01/2007

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Hull Royal Infirmary
Hull
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Sponsor information

Organisation
Record Provided by the NHSTCT Register - 2007 Update - Department of Health

Sponsor details
The Department of Health, Richmond House, 79 Whitehall
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Sponsor type
Government

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Funder(s)

Funder type
Government

Funder Name
The North and South Bank Research and Development Consortium (UK), NHS R&D Support Funding

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/04/2006		Yes	No