

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

☐ Prospectively registered

☐ Protocol

Registration date

28/09/2007

Overall study status

Completed

☐ Statistical analysis plan

☒ Results

Last Edited

25/04/2012

Condition category

Pregnancy and Childbirth

☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr P Balaji

Contact details

Hull Royal Infirmary

Anlaby Road

Hull

United Kingdom

HU3 2JZ

Additional identifiers

Protocol serial number

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% Levobupivacaine 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

Primary study design

Interventional

Study design

Prospective randomised single blind study

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

Not provided at time of registration

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

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

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

United Kingdom

England

Study participating centre

Hull Royal Infirmary

Hull

United Kingdom

HU3 2JZ

Sponsor information

Organisation

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

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

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