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The effect of the Oxford Head Elevating Laryngoscopy Pillow (OHELP), on spinal anaesthesia in elective caesarean sections

Submission date
22/11/2013

Recruitment status
No longer recruiting

Registration date
31/01/2014

Overall study status
Completed

Last Edited
31/01/2014

Condition category
Pregnancy and Childbirth

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Head Elevating Laryngoscopy Pillow (HELP) was introduced recently to the National Maternity Hospital and since then it has been a routine measure of safety in obese patient airway management; however, its impact on local anaesthetic effect post spinal anaesthesia is still unknown. The pillow is used routinely for obese mothers, and there are no obvious safety concerns with it.
The pillow is usually placed under the head and shoulders, and it changes the angle of the airway, making it easier to access the patients airway without moving the patient in the rare case that a general anaesthetic is needed.
Since the pillow changes the angle of the upper body, it might affect the spread of the local anaesthetic that is given for caesarean sections, and this initial study has been designed to investigate whether this might be the case. Since there is the possibility that use of the pillow will slow the spread of the anaesthetic, a catheter will be left in so that top-up doses can be administered easily.

Who can participate?
Expectant mothers, gestational age > 32 weeks and undergoing elective caesarean section.

What does the study involve?
Participants will be randomly allocated to one of two groups.
The intervention group will lie on an Oxford Head Elevating Laryngoscopy Pillow and a standard head pillow.
The control group will use only a standard head pillow. We will then compare the two groups of mothers to see whether they achieved a satisfactory level of anaesthetic block (numbness to touch) after 10 minutes.
We will also be investigating the number of women from each group that required conversion to general anaesthetic, and we will compare whether top-up doses of anaesthetic will be required.

What are the possible benefits and risks of participating?
The outcome of the study will hopefully be to establish whether the benefits of the pillow

easier airway management in case of general anaesthetic might not outweigh any disadvantages such as poor anaesthesia leading to discomfort or pain during the procedure, or even increasing the rate of requiring general anaesthetic. Since there is no evidence one way or the other at the moment, and the pillow is in routine use, it is important
that this issue be investigated.

Where is the study run from?
The National Maternity Hospital, Ireland.

When is the study starting and how long is it expected to run for?
The study started in June 2013 and ran until October 2013.

Who is funding the study?
National Maternity Hospital, Ireland.

Who is the main contact?
Dr Hayat Elfil

Contact information

Type(s)
Scientific

Contact name
Dr Hayat Elfil

Contact details
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
The effect of the Oxford Head Elevating Laryngoscopy Pillow (OHELP), on subarachnoid local anesthetic spread in elective caesarean sections

Acronym
OHELP

Study objectives
That the Oxford Head Elevating Laryngoscopy Pillow slows the cephalad spread of local anaesthetic and therefore delays the onset of satisfactory sensory blockade (T6 or better) to perform caesarean section.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Research Ethics Committee - National Maternity Hospital, 30/04/2013

Study design
Single-centre prospective randomised controlled trial with two non-blinded parallel arms

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
Extent of sensory block in females undergoing elective caesarean section for a singleton pregnancy, and receiving combined spinal-epidural (CSE) anaesthetic at L3/4

Interventions
Intervention group and a control group from consecutively eligible parturients.

The intervention group will lie on an Oxford Head Elevating Laryngoscopy Pillow and a standard head pillow .

The control group will use only a standard head pillow.

A seated position will be adopted for the neuraxial blockade performance. Combined Spinal Epidural will be administered at L3/4 (by palpating iliac crests). The operating theatre table will be held in the zero position (completely horizontal with no head elevation). The epidural space will be located using the loss of resistance to air (NOT saline) technique. The subarachnoid space will be located using the needle through needle technique.

Intrathecal injection will consist of 2.2 ml of hyperbaric Bupivacaine 0.5% and Fentanyl 15 micrograms + Morphine 100 micrograms. The epidural catheter will be left at 4 cm in the epidural space, but nothing will be injected via epidural catheter unless there is a block failure.

Left uterine displacement held at 20 degrees facilitated by Cardiff wedge support.

Block failure is defined as sensory block not reaching T6 (defined as level of xiphisternum) within 10 mins, in which case the patient will be given epidural boli of 5 ml Lignocaine 2% + Adrenaline 1:200,000 until block is satisfactory.

Patients were closely monitored post their caesrean sections for their sensory and motor block until they were able to move their legs and were haemodynamically stable. This took around one hour on average.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Sensory block will be assessed at 10 min post subarachnoid anesthesia induction (time 0) using loss of touch sensation to ethyl chloride sprayed bilaterally in the midclavicular line. The ethyl chloride spray container will be 5 cm from the patient's skin, and a continuous jet will be sprayed as the container is moved in a cranial direction.

Primary outcome measure is a binary variable defined as lack of sensory block on the right or the left, below T6, versus bilateral block at least as high as T6.

Measured at 10 min from the baseline.

Secondary outcome measures
1. Conversion to general anaesthetic for any reason
2. Administration of a top-up dose of anaesthetic of any sort

Measured at the baseline

Overall study start date
01/06/2013

Completion date
15/10/2013

Eligibility

Key inclusion criteria
All parturients agreeing to participate in the trial where are these criteria are met:
1. Elective caesarean section where there is no fetal or maternal compromise
2. Singleton pregnancy
3. Gestational age > 32 weeks

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
100 (50 per arm)

Key exclusion criteria
1. Refusal to consent
2. Parturients opting for GA or with medical conditions preventing neuraxial anaesthesia
3. Emergency caesarean sections where there is fetal or maternal compromise (Lucas Grade 1 and 2)
4. Multiple pregnancy
5. Gestational age < 32 weeks
6. Body mass index (BMI) > 40

Date of first enrolment
01/06/2013

Date of final enrolment
15/10/2013

Locations

Countries of recruitment
Ireland

Study participating centre
Dept. of Anaesthesiology
Dublin
Ireland
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Sponsor information

Organisation
The National Maternity Hospital (Ireland)

Sponsor details

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Ireland
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Sponsor type
Hospital/treatment centre

Website
http://www.nmh.ie

ROR
https://ror.org/03jcxa214

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
National Maternity Hospital (Ireland)

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