

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

<b>Submission date</b> 22/11/2013	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 31/01/2014	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 31/01/2014	<b>Condition category</b> Pregnancy and Childbirth	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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

Dept. of Anaesthesiology  
National Maternity Hospital  
Holles Street  
Dublin  
Ireland  
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## Additional identifiers

### Protocol serial number

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

### **Study type(s)**

Treatment

### **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 caesarean 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(s)**

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.

**Key secondary outcome(s)**

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

Measured at the baseline

**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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

Female

**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)

**ROR**

<https://ror.org/03jcx214>

## **Funder(s)**

**Funder type**

Hospital/treatment centre

**Funder Name**

National Maternity Hospital (Ireland)

## **Results and Publications**

## **Individual participant data (IPD) sharing plan**

### **IPD sharing plan summary**

Not provided at time of registration