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Measurement of epidural pressures in parturients

Submission date
19/08/2014

Recruitment status
No longer recruiting

Registration date
02/09/2014

Overall study status
Completed

Last Edited
19/02/2020

Condition category
Pregnancy and Childbirth

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

Plain English summary of protocol

Background and study aims
Epidurals can result in serious complications. These include infections of the spine spinal and injury to nerves in the spine. About 1% of patients who have an epidural suffer what is called a post-dural puncture headache, a headache that develops after injection of an epidural. This can be extremely disabling. The risks of injury in very overweight (obese) women are increased due to technical difficulties. Changes to the training structure of the junior anaesthetists giving the injection and also the need for compliance with the European Working Time Directive (resulting in reduced training opportunities) further worsen this situation. Here, we want to find out about the pressure required to reach the epidural space when inserting an epidural needle into pregnant women of varying weights. Correlation will then be made with ultrasound and Magnetic Resonance Imaging (MRI) scans of their lower spine. The plan is to use the results gained to create a computer graphics and physical epidural injection simulator. This simulator will be used by anaesthetists to practice the epidural technique before performing on pregnant women.

Who can participate?
The study aims to recruit pregnant women with body mass indices (BMIs) that fall within four groups: 18-24.9; 25-34.9; 35-44.9 and over 45. The women will be recruited before they go into labour and also in early labour if they have expressed a desire to have an epidural. .

What does the study involve?
BMI will be calculated using height and weight.The women will be grouped accordingly. An ultrasound scan of the lower back will be performed before insertion of the epidural. If the woman then requests an epidural, the pressure applied to the epidural needle will be measured using a specific sensor attached to the needle. As the anaesthetist inserts the epidural, the change in pressures will be recorded wirelessly and the data transmitted to a distant computer. Following the epidural procedure, an MRI scan of the lower spine will be performed within 72hrs of the patient giving birth and these images will be used for computer animation modelling. This will be performed at a convenient time for the mother following delivery of the baby.

What are the possible benefits and risks of participating?
There will be no immediate benefits to those taking part but the data collected will be used to

help to train future anaesthetists acquire the skills and knowledge for epidural insertion. The equipment used comes from standard sterile epidural packs and the pressure sensing device uses a three-way tap that also comes from a sterile pack. Due to the addition of this extra piece of equipment there is a theoretical increased risk of infection, although this is extremely small. However, please bear in mind that the risk of infection following an epidural ranges from 1 in 80,000 to 1 in 300,000. Ultrasound and MRI scans are non-invasive, painless procedures and are considered harmless.

Where is the study run from?
The study has been set up by Poole Hospital NHS Foundation Trust, UK. Poole Maternity Unit will be where the practical elements of the research will occur.

When is study starting and how long is it expected to run for?
The recruitment started in September 2012 and lasted for one year.

Who is funding the study?
National Institute of Academic Anaesthesia, UK.

Who is the main contact?
Prof Michael Wee, mike.wee@poole.nhs.uk
Dr Richard Isaacs, richard.isaacs@uhs.nhs.uk

Contact information

Type(s)
Scientific

Contact name
Prof Michael Wee

Contact details
Dept of Anaesthesia
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Poole
United Kingdom
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
P110504

Study information

Scientific Title
Quantification of the pressures generated during insertion of an epidural needle and subsequent imaging of the epidural space in labouring women of varying body mass indices

Study objectives
The primary aim is to measure the resultant pressure exerted on an epidural needle as it is advanced through the interspinous ligament and ligamentum flavum of parturients with increasing body mass indices.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee South Central - Portsmouth, 13/06/2011, ref: 11/SC/0196

Study design
Single-centre observational study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
The patient information sheet is available upon request

Health condition(s) or problem(s) studied
Epidural anaesthesia

Interventions
This study will only involve women who have requested to have an epidural as part of their birth plan. All of the epidural procedures will be carried out on the labour ward of Poole Maternity Unit by two experienced anaesthetists using standard equipment. To collect the pressure data we will attach a small electronic sensor onto the epidural needle. As the anaesthetist advances the needle through the ligaments, the electronic sensor will pick up the pressure readings and transfer data wirelessly back to a computer or recording device. An ultrasound of the lower spine will also be performed prior to the epidural, followed by a magnetic resonance imaging (MRI) scan of the spine after delivery. This data will also be used to create the epidural simulator based on patient-specific measurements. These measurements and images will lead to the development of a novel epidural simulator to help train novice and experienced anaesthetists with difficult epidurals.

Intervention Type

Other

Phase
Not Applicable

Primary outcome measure
The primary aim is to measure the pressures required to reach the epidural space when inserting an epidural needle into pregnant women of varying body mass indices. Graphical displays of the pressures will then be produced.

Secondary outcome measures
Correlation will then be made with ultrasound and Magnetic Resonance Imaging (MRI) scans of their lower spine. The aim will be to create a computer graphics and physical epidural injection simulator. This simulator will be used by anaesthetists to practice the epidural technique in a controlled environment.

Overall study start date
01/09/2012

Completion date
01/09/2013

Eligibility

Key inclusion criteria
1. ASA I or II (healthy) women aged 18-40 inclusive
2. Women having first child or any subsequent children (primi and multiparous)
3. Women in early active labour or prior to induction of labour who have requested epidural analgesia or been advised by the medical team to have an epidural
4. Singleton pregnancies (i.e. not twins etc)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
40 Years

Sex
Female

Target number of participants
20

Total final enrolment

Key exclusion criteria
1. Any of the usual contraindications to epidural anaesthesia
2. Known spinal abnormalities
3. Previous back surgery
4. History of connective tissue disorder
5. Difficult epidural insertion requiring more than 3 attempts
6. Women who already have an epidural in-situ and need a re-site for inadequate block
7. Women with inadequate comprehension of the English language and poor communication skills

Date of first enrolment
01/09/2012

Date of final enrolment
01/09/2013

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Dept of Anaesthesia
Poole
United Kingdom
BH15 2JB

Sponsor information

Organisation
Poole Hospital NHS Foundation Trust (UK)

Sponsor details
Longfleet Road
Poole
England
United Kingdom
BH15 2JB

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/03kdm3q80

Funder(s)

Funder type
Research organisation

Funder Name
National Institute of Academic Anaesthesia (UK) (Obstetric Anaesthetists' Association Large Project Grant) July 2012 (ref: WKR0-2012-0035)

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		01/12/2017	19/02/2020	Yes	No