

A study of maternal recall of risk information given prior to regional analgesia

Submission date 12/09/2003	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 12/09/2003	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 16/12/2014	Condition category 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
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N0047111205

Study information

Scientific Title
A study of maternal recall of risk information given prior to regional analgesia

Study objectives

What is the baseline ability to recall risk information and can this be improved by changing the way the information is imparted to mothers? This will be tested by giving mothers a consent form to read which contains the risk information.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Pregnancy and Childbirth: Regional analgesia

Interventions

Recruitment - Mothers will be approached in antenatal clinic (34 week appointment). All mothers who have no previous experience of epidurals will be eligible. Patient information sheets will be given to them and if they are interested then they will be asked to sign a consent form.

Randomisation - If the mothers then want an epidural during labour, they will be randomised by the on call registrar anaesthetist by picking a trial envelope. Half will contain a blank piece of paper and the other half will have consent for epidural analgesia forms. Group A (blank paper) - These mothers will be treated normally by receiving the risk information verbally from the anaesthetist before they take verbal consent for the epidural. Group B (consent form) - This group of mothers will receive the same verbal information whilst they read the consent form. They will sign a written consent for epidural analgesia. Interview - There is a normal daily ward round of all patients who have received anaesthetic input in the previous 24 h. All study patterns will be followed up on this ward round. They will receive the normal follow up AFTER they have been asked how many pieces of risk information they can correctly recall. The interviewer will be blinded as to which group the patient is in. Analysis - The data will be collated, anonymised and analysed to give us the average scores of each group along with any trend information present.

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

To improve the recall of risk information on women receiving regional analgesia (epidural).

Key secondary outcome(s)

Not provided at time of registration

Completion date

01/04/2004

Eligibility

Key inclusion criteria

Not provided at time of registration

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

01/04/2002

Date of final enrolment

01/04/2004

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Birmingham Women's Hospital

Birmingham

United Kingdom

B15 2TG

Sponsor information

Organisation

Department of Health (UK)

Funder(s)**Funder type**

Hospital/treatment centre

Funder Name

Birmingham Women's Healthcare NHS Trust (UK)

Results and Publications**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration