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

Submission date	Recruitment status	[ ] Prospectively registered
12/09/2003	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
12/09/2003	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
16/12/2014	Pregnancy and Childbirth	[ ] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/04/2002

Completion date
01/04/2004

Eligibility

Key inclusion criteria
Not provided at time of registration

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
Aim is to have 150 patients in both groups.

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
England

United Kingdom

Study participating centre
Birmingham Women's Hospital
Birmingham
United Kingdom
B15 2TG

Sponsor information

Organisation
Department of Health (UK)

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
http://www.doh.gov.uk

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Birmingham Women's Healthcare NHS Trust (UK)

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