ISRCTN49349244 https://doi.org/10.1186/ISRCTN49349244

COMET: Comparative Mobile Epidural Trial

Submission date
23/01/2004

Recruitment status
No longer recruiting

Registration date
23/01/2004

Overall study status
Completed

Last Edited
21/12/2009

Condition category
Pregnancy and Childbirth

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

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
MCH 02-19

Study information

Scientific Title
A randomised controlled trial of two types of epidural analgesia evaluating short and long term outcomes, including backache

Acronym
COMET

Study objectives
Using a randomised controlled design we propose to investigate
1. Whether an epidural technique which provides minimal motor block is associated with differences in the more traditional technique and
2. Whether there are any variations in these respects between two different types of minimal motor block epidural techniques

Please note that as of 21/12/09, this record was updated to include information on ethics approval, target number of participants and publications.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approval received from Birmingham and Leicester research ethics committees (added 21/12/09)

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Childbirth

Interventions
1. Standard epidural
2. Mobile combined spinal-epidural
3. Mobile 'Boston' epidural.

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
Not provided at time of registration

Key secondary outcome(s)
Not provided at time of registration

Completion date
01/10/2001

Eligibility

Key inclusion criteria
Women who have decided to have an epidural. Patient consent to take part in the trial can only be fully given at the time of deciding to have an epidural, but to avoid 'cold' decision making in labour an explanatory leaflet will be provided for all primiparae at the last routine hospital antenatal visit (approximately 34 weeks). Only primigravida will be recruited in order to make a meaningful comparison of obstetric performance, given the profound effect of parity on the main outcome measure, and to avoid 'contamination' of experience and recall of backache after previous deliveries.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

Key exclusion criteria
Women who require regional block anaesthesia for an elective section or for imminent operative delivery will be excluded. Additionally, those who have contra-indications to spinal or epidural analgesia (e.g. coagulopathy, cardiomyopathy, valvular cardiac disease, abnormal vertebral anatomy, etc) or to any drug in the study will also be excluded.

Date of first enrolment
01/07/1997

Date of final enrolment
01/10/2001

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Department of Public Health and Epidemiology
Birmingham
United Kingdom
B15 2TT

Sponsor information

Organisation
Record Provided by the NHS R&D 'Time-Limited' National Programme Register - Department of Health (UK)

Funder(s)

Funder type
Government

Funder Name
NHS Mother and Child Health National Research and Development Programme (UK)

Results and Publications

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	results	07/07/2001		Yes	No
Results article	results	01/12/2002		Yes	No
Results article	results on urinary catheterisation with anaesthesia	01/01/2009		Yes	No
Results article	results on ambulation in labour and delivery mode with anaesthesia	01/03/2009		Yes	No
Results article	results	01/01/2010		Yes	No