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

COMET: Comparative Mobile Epidural Trial

Submission date 23/01/2004	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 23/01/2004	**Overall study status** Completed	
Last Edited 21/12/2009	**Condition category** Pregnancy and Childbirth	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Christine MacArthur

Contact details
Department of Public Health and Epidemiology
Medical School
University of Birmingham
Edgbaston
Birmingham
United Kingdom
B15 2TT
+44 (0)121 4146770
c.macarthur@bham.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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)

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
Childbirth

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

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/07/1997

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

Age group
Adult

Sex
Female

Target number of participants
1050 (added 21/12/09

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
England

United Kingdom

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)

Sponsor details
The Department of Health
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

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

Funder(s)

Funder type
Government

Funder Name

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	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