

COMET: Comparative Mobile Epidural Trial

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

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

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)

Study design

Randomised controlled trial

Primary study design

Interventional

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