

# COMET: Comparative Mobile Epidural Trial

<b>Submission date</b> 23/01/2004	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 23/01/2004	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 21/12/2009	<b>Condition category</b> Pregnancy and Childbirth	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

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### Contact details

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## 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?
<a href="#">Results article</a>	results	07/07/2001		Yes	No
<a href="#">Results article</a>	results	01/12/2002		Yes	No
<a href="#">Results article</a>	results on urinary catheterisation with anaesthesia	01/01/2009		Yes	No
<a href="#">Results article</a>	results on ambulation in labour and delivery mode with anaesthesia	01/03/2009		Yes	No
<a href="#">Results article</a>	results	01/01/2010		Yes	No