ISRCTN21230935 https://doi.org/10.1186/ISRCTN21230935

# Randomised, double-blind, controlled study of combined spinal epidural (CSE) analgesia for labour with and without epidural volume extension (EVE).

**Submission date**
30/09/2004

**Recruitment status**
Stopped

**Registration date**
30/09/2004

**Overall study status**
Stopped

**Last Edited**
31/07/2009

**Condition category**
Pregnancy and Childbirth

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

**Contact name**
Dr Gary Stocks

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**

N0016127111

# Study information

### Scientific Title

### Study objectives
Whether using the CSE technique with EVE, can achieve the same quality of analgesia but with a quicker onset of action, and reduce the degree of unwanted motor block currently experienced in a proportion of patients.

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
Not provided at time of registration

### Study design
Randomised double blind controlled trial

### Primary study design
Interventional

### Secondary study design
Randomised controlled trial

### Study setting(s)
Hospital

### Study type(s)
Other

### Participant information sheet

### Health condition(s) or problem(s) studied
Pregnancy and Childbirth: Analgesia

### Interventions
As of 29/07/09 the status of this trial was changed to 'stopped'. This trial was never commenced.

Not provided at time of registration.

### Intervention Type
Other

### Phase
Not Specified

### Primary outcome measure

To improve our existing CSE labour analgesia, in terms of rapidity of onset of action and decreased motor block in the lower limbs allowing earlier ambulation.

### Secondary outcome measures
Not provided at time of registration

### Overall study start date
01/07/2003

### Completion date
31/07/2004

### Reason abandoned (if study stopped)
Objectives no longer viable

## Eligibility

### Key inclusion criteria
Not provided at time of registration

### Participant type(s)
Patient

### Age group
Adult

### Sex
Female

### Target number of participants
0

### Key exclusion criteria
Does not match inclusion criteria

### Date of first enrolment
01/07/2003

### Date of final enrolment
31/07/2004

## Locations

### Countries of recruitment
England

United Kingdom

**Study participating centre**
**Department of Anaesthesia**
London
United Kingdom
W6 8RF

# Sponsor information

**Organisation**
Department of Health

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

**Sponsor type**
Government

**Website**
http://www.dh.gov.uk/Home/fs/en

# Funder(s)

**Funder type**
Hospital/treatment centre

**Funder Name**
Hammersmith Hospital 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