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
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Additional identifiers

Protocol serial number
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

Primary study design
Interventional

Study design
Randomised double blind controlled trial

Study type(s)
Other

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(s)
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.

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

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

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

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
United Kingdom

England

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

Sponsor information

Organisation
Department of Health

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Hammersmith Hospital NHS Trust (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration