Does the use of a lower lumbar interspace for spinal anesthesia affect the efficacy of the block and maternal satisfaction?

Submission date 30/09/2004	Recruitment status No longer recruiting	 Prospectively registered Protocol
Registration date 30/09/2004	Overall study status Completed	 Statistical analysis plan Results
Last Edited 01/05/2015	Condition category Pregnancy and Childbirth	 Individual participant data Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s) Scientific

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers N0047129269

Study information

Scientific Title

Does the use of a lower lumbar interspace for spinal anesthesia affect the efficacy of the block and maternal satisfaction?

Study objectives

To find out whether spinal anaesthesia at the perceived L4-5 interspace is just as efficacious as that performed at the usual perceived L3-4 interspace, both clinically and for maternal satisfaction.

Ethics approval required Old ethics approval format

Ethics approval(s) Not provided at time of registration

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 Pregnancy and Childbirth: Anaesthesia

Interventions

Each volunteer will undergo normal clinical practice with the exception of random allocation to either the L3-4 or L4-5 interspace for insertion of spinal anesthetic. They will also be required to fill out a satisfaction questionnaire the day after delivery.

Intervention Type Drug

Phase Not Applicable

Primary outcome measure

That spinal anaesthesia at the perceived L45 interspace is just as efficacious as that performed at the perceived L3-4 interspace, both clinically and for maternal satisfaction.

Secondary outcome measures

Not provided at time of registration

Overall study start date 30/06/2003

Completion date 30/07/2004

Eligibility

Key inclusion criteria

60 volunteers. All of whom will be having an elective caesarean under spinal anaesthesia and do not have any significant medical problems.

Participant type(s) Patient

Age group Adult

Sex Female

Target number of participants 60

Key exclusion criteria Not provided at time of registration

Date of first enrolment 30/06/2003

Date of final enrolment 30/07/2004

Locations

Countries of recruitment England

United Kingdom

Study participating centre

Birmingham Women's Hospital Birmingham United Kingdom B15 2TH

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 Government

Funder Name Birmingham Women's Healthcare 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