Randomised controlled trial to assess the difference of spinal anaesthesia versus general anaesthesia in hip replacement surgery

Submission date	Recruitment status	Prospectively registered	
12/03/2007	No longer recruiting	☐ Protocol	
Registration date	Overall study status	Statistical analysis plan	
13/08/2007	Completed	[X] Results	
Last Edited	Condition category	Individual participant data	
10/06/2016	Musculoskeletal Diseases		

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

R&D/2007/08

Study information

Scientific Title

Randomised controlled trial to assess the difference of spinal anaesthesia versus general anaesthesia in hip replacement surgery

Study objectives

Spinal anaesthesia is as good as general anaesthesia in hip replacement surgery.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Hertfordshire 2 Research Ethics Committee, 05/02/2007, ref: 06/Q0204/137

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

Hip fracture

Interventions

Intervention 1: Spinal anaesthesia with injection of 2 ml 0.5% bupivicaine Intervention 2: General anaesthesia: femoral nerve block using 30 ml of 0.25% bupivicaine, induction with propofal and fentanyl 1 mcg/kg and maintenance with nitrous oxide/oxygen and isoflurothane

Follow up will be for the duration of the hip replacement surgery until fully conscious and for the subsequent in patient hospitalisation. Subsequent follow up will be at six weeks and one year.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Pain will be assessed by asking open questions and performing an assessment of the amount of analgesia required.

Secondary outcome measures

- 1. Mobility will be assessed by using a specially designed questionnaire
- 2. Confusion will be assessed by using the Mini Mental Questionnaire

Overall study start date

01/04/2007

Completion date

31/12/2013

Eligibility

Key inclusion criteria

- 1. Acute hip replacement surgery
- 2. Aged greater than 49

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

600

Key exclusion criteria

- 1. Conservative treatment for hip fracture
- 2. Unsuitable for spinal or general anaesthesia

Date of first enrolment

01/04/2007

Date of final enrolment

31/12/2013

Locations

Countries of recruitment

England

United Kingdom

Study participating centre Peterborough and Stamford Hospitals Foundation NHS Trust

Peterborough United Kingdom PE3 6DA

Sponsor information

Organisation

Peterborough and Stamford Hospitals NHS Foundation Trust (UK)

Sponsor details

Thorpe Road Peterborough England United Kingdom PE3 6DA

Sponsor type

Hospital/treatment centre

Website

http://www.peterboroughhospitals.co.uk/page_viewer.asp?category=Home&sid=8

ROR

https://ror.org/03kv8xc26

Funder(s)

Funder type

Government

Funder Name

Peterborough and Stamford Hospitals NHS Foundation Trust R&D Department (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 summaryNot provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/08/2015		Yes	No