

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

Submission date 12/03/2007	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 13/08/2007	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 10/06/2016	Condition category Musculoskeletal Diseases	<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

Protocol serial number

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

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Hip fracture

Interventions

Intervention 1: Spinal anaesthesia with injection of 2 ml 0.5% bupivacaine

Intervention 2: General anaesthesia: femoral nerve block using 30 ml of 0.25% bupivacaine, induction with propofol 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(s)

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

Key secondary outcome(s)

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

Completion date

31/12/2013

Eligibility

Key inclusion criteria

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

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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**

United Kingdom

England

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)

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

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?
Results article	results	01/08/2015		Yes	No