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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

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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 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