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A pilot study of a trial of tight control of blood pressure during hip fracture surgery in older people

Submission date
30/08/2016

Recruitment status
No longer recruiting

Registration date
30/08/2016

Overall study status
Completed

Last Edited
14/01/2019

Condition category
Circulatory System

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Around 70,000 mainly elderly people will have a hip fracture every year in the UK. It has a significant impact on the individual, families, carers and the health service. Recent studies have shown that there is a link between low blood pressure during surgery and worse outcomes afterwards. It is currently not known whether the low blood pressure is the cause of the problems or simply a sign of patients who become unwell following surgery. The study team hopes to undertake a large trial of tight control of blood pressure to see whether it makes a difference to major complications after surgery such as heart attack, stroke, confusion and kidney injury. Before this however, it is important to undertake a small study to find out if a large trial would be feasible. The aim of this study is to find out whether it is feasible to conduct a study looking at whether controlling blood pressure within tight limits during hip fracture surgery lead to fewer major complications (heart, brain and kidney individually) in the first week after surgery.

Who can participate?
Patients aged 70 and over who have a broken hip that requires surgery.

What does the study involve?
Participants are randomly allocated to one of two groups. Both groups of patients receive standard surgical care, anaesthesia (being put to sleep for surgery) and after-surgery care. Those in the first group receive drugs and intravenous (through a drip) fluids to keep their blood pressure within quite tight limits during their surgery. Those in the second group receive standard care (which involves receiving drugs and fluids according to the clinical opinion of the doctors looking after them in surgery). Over the following seven days, participants in both groups receive daily blood tests to find out if they are showing signs of heart or kidney damage and are assessed for signs of confusion (brain damage). One month later, participants receive a follow up phone call to check on health status and where they are living. Survival is also followed up at these times and then one year later through reviewing medical records.

What are the possible benefits and risks of participating?
There are no direct benefits or risks involved with participating in this study.

Where is the study run from?
Queen's Medical Centre (lead centre), Royal Sussex County Hospital and Peterborough City Hospital (UK)

When is the study starting and how long is it expected to run for?
January 2015 to February 2019

Who is funding the study?
National Institute of Academic Anaesthesia (UK)

Who is the main contact?
Dr Iain Moppett
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
30629

Study information

Scientific Title
Hip fracture intervention study for prevention of hypotension (HIP-HOP) trial: pilot study

Acronym
HIP-HOP

Study objectives
The aim of this study is to investigate the feasibility of recruiting participants to a study looking at whether reducing the amount of hypotension (number, severity and duration of episodes) during anaesthesia for hip fracture surgery decreases the frequency of delirium, heart abnormalities and kidney failure within five days after the operation.

Ethics approval required
Old ethics approval format

Ethics approval(s)
East Midlands - Nottingham 1 Research Ethics Committee, 13/04/2016, ref: 16/EM/0036

Study design
Randomised; Interventional; Design type: Treatment, Drug, Complex Intervention, Surgery

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Specialty: Injuries and emergencies, Primary sub-specialty: Injuries and emergencies; UKCRC code/ Disease: Injuries and Accidents/ Injuries to the hip and thigh

Interventions
Participants are randomised to one of two groups in blocks of unequal size, stratified by intended mode of anaesthesia and Nottingham Hip Fracture Score (≤4 vs >4).

Participants in both groups will undergo hip fracture surgery and rehabilitation in accordance with national and local standards of care.

Intervention group: Participants will receive active treatment as required to maintain both of the following:
1. SAP > 80% of baseline preoperative value
2. MAP > 75 mm Hg throughout
The order and doses of treatments to achieve this will depend upon the clinical scenario but will include:
1. Fluid bolus to ensure adequate intravascular volume (associated with reduced requirement for vasoactive drugs11)
2. Combined beta / alpha-1 adrenergic agonist (ephedrine)
3. More selective alpha-1 adrenergic agonist (metaraminol)
Blood pressure will be measured using standard non-invasive equipment every 2.5 minutes, or continuous non-invasive blood pressure monitoring (Nexfin, CNAP) throughout.

Control group: Participants receive standard blood pressure control, which involves the administration of fluids and vasopressor drugs deemed clinically appropriate by the attending anaesthetist during surgery. Frequency of blood pressure monitoring will be at the attending anaesthetist's discretion, but at least every 5 minutes.

Study participants will be participating in the study for seven days whilst in hospital with a telephone follow-up at 30 days. Mortality at one year will be retrieved from central records.

Intervention Type
Other

Primary outcome measure
Composite of presence or absence of defined cardiovascular, renal and delirium morbidity is measured daily for 7 days post-surgery using blood testing, clinical observations, and medical record review.

Secondary outcome measures
Clinical outcomes:
1. Presence or absence of each of defined cardiovascular, renal and delirium morbidity is measured daily for 7 days post-surgery using blood testing, clinical observations, and medical record review
2. Prevalence bone cement implantation syndrome will be measured using the Donaldson grading tool recorded during anaesthesia and surgery
3. Postoperative mortality is measured 5 and 30 days, and 1 year through medical record review
4. Quality of life is measured using the EQ-5D questionnaire 30 days post-surgery

Feasibility outcomes:
1. Recruitment rate is recorded as the number of eligible participant who consent to participate in the study by 12 months
2. Protocol efficacy will be measured by recording arterial blood pressure intraoperatively and determining
2.1. The lowest arterial blood pressure (systolic, mean and diastolic) value following induction of anaesthesia; and
2.2. Time below threshold values (Mean arterial pressure 75mmHg, 80% pre-op mean arterial pressure)

Overall study start date
19/01/2015

Completion date
01/02/2019

Eligibility

Key inclusion criteria
1. Aged over 70 years
2.
Unilateral hip fracture requiring hemiarthroplasty, dynamic hip screw, proximal femoral nail fixatio

3. Able to provide consent for trial participation

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Planned Sample Size: 75; UK Sample Size: 75. Final Sample Size: 75.

Key exclusion criteria
1. Patients due to undergo total hip arthroplasty
2. Patients with peri-prosthetic fractures
3. Patients without capacity
4. Pre-operative elevated troponin (measured for clinical reasons)

Date of first enrolment
01/10/2016

Date of final enrolment
01/10/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Queen’s Medical Centre
Nottingham University Hospitals NHS Trust
Derby Road
Nottingham

United Kingdom
NG7 2UH

Study participating centre
Royal Sussex County Hospital
Brighton and Sussex University Hospitals NHS Trust
Eastern Road
Brighton
United Kingdom
BN2 5BE

Study participating centre
Peterborough City Hospital
Edith Cavell Campus
Peterborough and Stamford Hospitals NHS Trust
Bretton Gate
Peterborough
United Kingdom
PE3 9GZ

Sponsor information

Organisation
University of Nottingham

Sponsor details
Research and Graduate Services
King's Meadow Campus
Lenton Lane
Nottingham
England
United Kingdom
NG7 2NR

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/01ee9ar58

Funder(s)

Funder type
Research organisation

Funder Name
National Institute of Academic Anaesthesia

Results and Publications

Publication and dissemination plan
Planned publication in a peer reviewed scientific journal

Intention to publish date
01/06/2019

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	25/07/2017		Yes	No
HRA research summary			28/06/2023	No	No