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REGARD: Comparing regional and general anaesthesia and their effect on delirium in patients with hip fractures

Submission date
02/10/2017

Recruitment status
No longer recruiting

Registration date
12/10/2017

Overall study status
Completed

Last Edited
01/06/2021

Condition category
Injury, Occupational Diseases, Poisoning

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

Plain English summary of protocol

Background and study aims
Patients who fall and sustain hip fractures are older and sometimes suffer from several health problems. Previous studies have shown that whilst some return to their previous quality of life, other patients do not recover well. For example some patients experience poor memory, feeling physically weak or they are not able to be as independent as they were before they fractured their hip. Patients who do not recover well have higher risk of developing complications after their operation. All patients undergoing surgery for hip fracture will be provided with anaesthesia. This research study is comparing the use of two standard types of anaesthetic (general anaesthesia – where the patient is are unconscious, regional anaesthesia – when the patient has nerve block and lightly sedated) for patients undergoing surgery for hip fractures. Research is needed to understand whether the type of anaesthesia may affect how well patients recover after surgery. To find out whether one type of anaesthesia is better, a large number of participants would be needed which would be very expensive. By carrying out this smaller scale study first, we will know whether it is possible to complete a larger study. There are some suggestions that patients given regional anaesthesia may recover better but this has not been thoroughly tested. It is not currently known whether one type of anaesthesia is better than the other. The aim of this study is to show whether a study on the effects of regional and general anaesthesia on delirium is feasible in patients with hip fractures.

Who can participate?
Adults aged 65 and older who have planned surgical treatment for a hip fracture.

What does the study involve?
Participants are assessed by the primary clinical team for eligibility after admission to hospital. Participants are further assessed by an anaesthetist to make sure that they are equally suitable for both regional and general anaesthetics. After the assessments have been completed, participants are asked to provide consent. Participants who consent to participate are randomised to one of two groups. Those in the first group receive regional anaesthetics. Those in the second group receive the general anaesthetic during their surgery. At 24 hours after the surgery, the participants are approached by the research nurse with more detailed information

about the trial. The participant has the opportunity to ask any questions before giving written consent. If the patient is unable to give consent, a personal or nominated consultee will be approached. Participants are followed up after seven days, at hospital discharge and after 120 days after surgery. At each time point, patients who were previously unable to give consent will be assessed for their ability to give consent.

What are the possible benefits and risks of participating?
There are no direct benefits or risks for those taking part in the study. Both anaesthetic options used in the trial are part of standard clinical practice. This means that patients are, in standard practice, almost equally as likely to receive general or regional anaesthetic. The difference for patients who are participating in the trial is that their data is collected and their results can influence future standard clinical practice. There have not been any direct comparisons between general and regional anaesthetic, so their comparative risks and benefits are unknown.

Where is the study run from?
1. Birmingham Heartlands Hospital
2. Queen's Hospital Burton
3. Warwick Hospital
4. Royal Stoke University Hospital (as of 04/10/2018)

When is the study starting and how long is it expected to run for?
May 2017 to February 2019 (updated 01/06/2021, previously: May 2017 to January 2019)

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
Dr Joyce Yeung
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Study website
https://www2.warwick.ac.uk/fac/med/research/hscience/ctu/trials/regard

Contact information

Type(s)
Public

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
35126

Study information

Scientific Title
A Feasibility Randomised Controlled Trial to compare REgional versus General Anaesthesia in Reducing Delirium in patients with Hip Fractures

Acronym
REGARD

Study objectives
The aim of this study is to show whether a trial on the effects of regional and general anaesthesia on delirium is feasible in patients with hip fractures. This research is designed to compare whether local or general anaesthesia makes a difference to how well someone recovers after hip surgery: in particular cognition (thinking and awareness) and physical function (mobility and quality of life).

Ethics approval required
Old ethics approval format

Ethics approval(s)
London - South East Research Ethics Committee, 27/07/2017, ref: 17/LO/1156

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

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 below 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
The REGARD study is a feasibility randomised control trial (RCT). REGARD is a small trial (n=100) looking to recruit patients aged over 65, who are about to undergo surgery for a fractured hip and are suitable to have either Regional Anaesthetic (RA) or General Anaesthetic (GA) during their surgery. The majority of patients that present to hospital with a hip fracture in this age group are often able to tolerate either type of anaesthetic but there is a lack of research into which type of anaesthetic is best for these patients. The study will look at incidence of post-operative delirium, pain, functional outcome and quality of life in participating patients up to 120 days post-surgery. The study aims to see if a larger randomised trial is possible using this trial design to inform standard clinical care practice within the UK.

If the condition of the patient has changed in the meantime and the clinical staff no longer consider the participant suitable for either anaesthetic, the participant will be treated according to their clinical needs. This means that if the participant is assigned to regional anaesthetic, but develops the need for a general anaesthetic before or during the operation, the participant will receive general anaesthetic.

The trial also includes a qualitative substudy that will look at the effectiveness of patient identification, screening and randomisation procedures. This aspect of the study will explore staff members' experience of being involved in the trial, as well as what they believe to be potential barriers and facilitators to recruitment.

Intervention Type
Other

Primary outcome measure
1. Proportion of eligible patients that are randomised are measured using records at study end
2. Proportion of patients/consultees providing agreement to ongoing study participation is measured using study records at end of study
3. Proportion of patients with complete follow-up data are measured suing study record at the end of the study

Secondary outcome measures
Current secondary outcome measures as of 01/06/2021:

Secondary feasibility outcomes:
1. Proportion of patients/consultees providing assent to ongoing study participation is measured using study records at end of study
2. Proportion of patients with complete follow-up data are measured using study record at the end of the study
Secondary patient outcomes:
1. Number of patients who develop post-operative delirium within 7 days using face to face

delirium screening tools (4A Tests, Richmond Agitation Sedation Scale, Abbreviate Mental Test Score) or medical notes review on Day 1, Day 2 and Day 7
2. Severity of post-operative delirium if present is measured using Memorial Delirium Assessment Scale (MDAS) on Day 1, Day 2 and Day 7
3. Acute pain using analgesic use and prescription chart review on Day 1, Day 2 and Day 7
4. Cognitive function is measured using Mini Addenbrookes Cognitive Examination (MACE, if patient completes) on Day of discharge. Cognitive Function is also collected using MACE or Informant Questionnaire on Cognitive Decline in the Elderly (IQCODE, if family/friend completes) on 120 day follow up
5. Post-operative complications is measured using Post-operative Morbidity Survey-Hip Fracture and medical notes review on Day 1, Day 2 and Day 7
6. Persistent delirium is screened using delirium screening tools and MDAS on 120 day follow-up
7. Quality of life is measured using EQ-5D-5L questionnaire on Day of discharge and 120 day follow up
8. Ability to perform daily activities is measured using Nottingham Extended Activities of Daily Living (NEADL) on 120 day follow-up
9. Length of hospital stay is measured using medical records on Day of discharge
10. Discharge location is measured using medical records on Day of discharge
11. In-hospital and 30 day mortality is measured using Notification of Death form or medical notes review on Day of discharge

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Previous secondary outcome measures:

1. Number of patients who develop post-operative delirium within 7 days post-randomisation in each group using delirium screening tools based on DSM-5 criteria
2. Type, severity and duration of delirium if present is measured using 4AT at baseline, postop day one, two, seven, 120 day follow-up, using RASS at postop day one, day two, 120 day follow up, AMTS is measured at postop day one, two, seven, 120 day follow up, MDAS is measured at postop day one, two, seven, 120 day follow up and MACE is measured at day of discharge, 120 day follow up.
3. Cognitive function is measured using IQ code at baseline, 120 day follow up
4. Acute pain is measured using EQ-5D at day of discharge/120 day follow up and is measured using the POMS-HS at day one, two and seven
5. Post-operative morbidity is measured using at 120 day follow up
6. Quality of life is measured using EQ-5D at day of discharge and 120 day follow up
7. Length of hospital stay is measured using at day of discharge
8. Discharge location is measured using at day of discharge
9. In-hospital and 30 day mortality is measured using Death form or day of discharge

Overall study start date
01/05/2017

Completion date
28/02/2019

Eligibility

Key inclusion criteria

1. Clinically or radiographically diagnosed intracapsular or extracapsular hip fracture
2. Planned surgical treatment via hemiarthroplasty, total hip arthroplasty or appropriate fixation procedure
3. Aged 65 years and over

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
Planned Sample Size: 100; UK Sample Size: 100

Total final enrolment
100

Key exclusion criteria
1. Multiple trauma or planned concurrent surgery not amenable to spinal anaesthesia
2. Absolute contraindication to regional anaesthesia:
2.1. Known or suspected congenital or acquired coagulopathy
2.2. Active use of pharmacological anticoagulants within a timeframe defined to contraindicate neuraxial block placement
2.3. Known or suspected unrepaired critical or severe aortic stenosis
2.4. Known or suspected active skin infection at the planned needle insertion site
2.5. Known or suspected elevated intracranial pressure contraindicating dural puncture; previous spinal surgery precluding RA, localised sepsis in lumbar spine, documented allergies to local anaesthetic
3. Known or suspected to be at elevated risk for malignant hyperthermia
4. Previous participation in the REGARD trial
5. Determination by the surgeon or the anaesthetist that the patient would not be suitable for randomisation
6. Patient not expected to survive beyond 48 hours

Date of first enrolment
05/10/2017

Date of final enrolment
18/09/2018

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Birmingham Heartlands Hospital
Borderley Green East
Birmingham
United Kingdom
B9 5SS

Study participating centre
Queen's Hospital Burton
Burton Hospitals NHS Foundation Trust
Belvedere Road
Burton on Trent
United Kingdom
DE13 0RB

Study participating centre
Warwick Hospital
South Warwickshire NHS Foundation Trust
Lakin Road
Warwick
United Kingdom
CV34 5BW

Study participating centre
Royal Stoke University Hospital
Newcastle Road
Stoke-on-Trent
United Kingdom
ST4 6QG

Sponsor information

Organisation
University of Warwick

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University House
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Coventry
England

United Kingdom
CV4 8UW

Sponsor type
University/education

ROR
https://ror.org/01a77tt86

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
The trial will be reported in accordance with the Consolidated Standards of Reporting Trials (CONSORT) guidelines extension to randomised pilot and feasibility study (www.consort-statement.org).
The plan of dissemination includes:
1. Publications in specialist journals, such as anaesthetic, trauma, geriatric journals and also high impact peer-reviewed general journals such as BMJ.
2. Results will be presented at national anaesthetic, geriatric and surgical meetings such as those organised by Age Anaesthesia Association, Health Service Research Centre UK Peri-operative Clinical Trials Network Research Forum, Royal College of Anaesthetists, Association of Anaesthetists in Great Britain and Ireland, British Geriatric Society, European Delirium Association and American Delirium Society meetings.
3. A layperson summary will be produced to inform public and patient groups by using our links

with National Osteoporosis Society and Clinical Research Ambassador Group at Public Involvement Team at Heart of England NHS Foundation Trust.

Intention to publish date
01/07/2021

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No