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World hip trauma evaluation four

Submission date	Recruitment status	[X] Prospectively registered
17/03/2016	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
17/03/2016	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
23/09/2021	Musculoskeletal Diseases	

Plain English summary of protocol

Background and study aims
Fractures of the proximal femur (hip fractures) are common, affecting almost 65,000 patients in England and Wales in 2013 and 1.31 million patients worldwide in 1990. They are more common in older people as they are more likely to have weakened, brittle bones (osteoporosis) and tend to result from a fall. In most cases, surgery is the only treatment option for hip fractures. This is usually done by lining up the broken pieces of bone and fixing them in place with screws or metal plates. The most common type of screw used to fix the fracture in the correct position is the sliding hip screw (SHS), which controls any movement, stabilising the fracture so that it can heal. When the bone is very weakened or if the fracture is very complex, the SHS may not be able to control movement as well, and so the fracture cannot heal properly. The XBolt dynamic plating system builds on the successful design features of the SHS but fixes to the hip bone differently using a new type of expanding bolt. The aim of this study is to find out find out if there is any difference to the quality of life of patients after surgery when they are treated with the Xbolt dynamic plating system or the traditional SHS.

Who can participate?
Adults aged 60 or over who have a fractured hip that would benefit from sliding hip screw fixation.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group undergo surgical fixation of their fracture using the SHS. Those in the second group undergo surgical fixation of their fracture using the Xbolt dynamic plating system. At the start of the study and then 4 and 12 months later, participants in both groups complete a questionnaire in order to find out if there has been any change to their quality of life and to find out which group shows the greater improvement.

What are the possible benefits and risks of participating?
There are no direct benefits involved with participating in the surgery. Any operation for a hip fracture carries some risks, but they are the same for both types of hip replacement and are faced by all patients facing a hip replacement. The risks of surgery include bleeding, risk of blood clots, risk of damage to nerves and blood vessels in the surgical area and the risk associated with the anaesthetic. Patients will have routine X-rays taken of their hip before and after the operation, to evaluate the hip replacement. The dose of radiation they will receive is equivalent

to around 2 months of normal background radiation and is the same for all patients who have a hip replacement for a hip fracture.

Where is the study run from?
John Radcliffe Hospital (UK)

When is the study starting and how long is it expected to run for?
February 2016 to June 2019

Who is funding the study?
X-Bolt Direct Ltd (UK)

Who is the main contact?
Dr Katy Mironov
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Study website
https://white4.octru.ox.ac.uk/

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Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
20668

Study information

Scientific Title
World Hip Trauma Evaluation Four: a randomised controlled trial of the sliding hip screw versus X--Bolt dynamic plating system for the fixation of trochanteric fractures of the hip

Acronym
WHiTE Four

Study objectives
The aim of this study is to investigate patients' quality of life after a X-Bolt Dynamic Plating System compared with the Sliding Hip Screw in the treatment of trochanteric fractures of the hip

Ethics approval required
Old ethics approval format

Ethics approval(s)
West Midlands – Coventry & Warwickshire Research Ethics Committee, 18/02/2016, ref: 16/WM /0001

Study design
Multi-centre randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

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
Topic: Injuries & Emergencies, Surgery; Subtopic: Injuries & Emergencies (all Subtopics), Surgery; Disease: Injuries & Emergencies, All Surgery

Interventions
Participants are randomly allocated to one of two groups. The allocation sequence will be administered by a distant computer generated sequence administered by clinical trials unit; allocation will be 1:1, stratified by centre with unequal block sizes.

Participants will usually be assessed in the Emergency Department. Diagnosis of a fracture of the proximal femur will be confirmed by a plain radiograph. Supplementary imaging will be at the discretion of the treating clinical team. Routine investigations, anaesthetic assessment, antibiotic and venous thromboembolic prophylaxis will used as per local policy.

Anaesthetic technique
A regional or general anaesthesia technique will be used for every participant. Intra-operative analgesia will be achieved by combining a local anaesthetic nerve block (femoral and lateral cutaneous nerve of the thigh, fascia iliaca or lumbar plexus) using either a nerve stimulator or ultrasound-guided technique, peri-articular anaesthetic infiltration, IV paracetamol 1g intravenous infusion and opiate analgesia as clinically indicated.

Surgical intervention
All participants will have an attempted closed reduction of their fracture. If satisfactory reduction cannot be achieved, the surgeon will proceed to open reduction. The lower limb will be supported on a fracture table. Internal fixation with either device will be performed following the manufacturer’s guidelines.

Group 1: Fixation will involve a SHS with a plate as long as the surgeon feels necessary to achieve adequate fixation in the femoral shaft. The use of supplementary fixation such as wires, cables, lag screws and trochanteric stabilisation plate attachments is permitted at the surgeon's discretion.

Group 2: Fixation will involve an X-Bolt dynamic plating system following the manufacturer's guidelines. Similar to the SHS group, the length of the plate will be at the surgeon's discretion. Supplementary fixation with wires, cables and lag screws are also permitted at the surgeon's discretion.

Post-operative analgesia will be prescribed intra-operatively and reviewed by the responsible clinical teams as appropriate.

In the post-operative period, participants will undergo an initial Physiotherapy and Occupational Therapy trauma assessment. A full social, cognitive, premorbid function and falls history will be obtained and documented. Participants will be given the relevant NHS Trust Patient Information packs. An initial treatment plan with objectives will be made, recorded and commenced. The aim of this plan will be for participants to mobilise through early, active, full weight bearing. Participants will be discharged from the acute Orthopaedic Trauma Ward at the earliest safe opportunity to the most appropriate discharge destination as determined by the multi-disciplinary team.

Intervention Type
Procedure/Surgery

Primary outcome measure
Participants' health status is measured using the EuroQol EQ-5D-5L questionnaire at baseline, 4 and 12 months post-surgery

Secondary outcome measures
1. Mortality rate is determined using patients' medical notes, at any point up to 12 months post-surgery
2. Functional status is assessed through patient interview/questionnaire at baseline, 4 and 12 months post-surgery
3. Revision surgery and cause is obtained from patients' medical notes, at any point up to 12 months post-surgery
4. Complications are obtained from patients' medical notes at baseline, and through patient interview/questionnaire at 4 and 12 months post-surgery
5. Radiographic outcomes, including screw migration and cut out, is collected from any x-rays taken as part of standard clinical follow-up during the first 12 months post-surgery

Overall study start date
01/01/2016

Completion date
18/09/2019

Eligibility

Key inclusion criteria

1. Patients presenting to the collaborative with trochanteric fracture of the hip
2. Those who, in the opinion of the treating surgeon, would benefit from sliding hip screw fixation
3. Aged 60 years and over

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Planned Sample Size: 1128; UK Sample Size 1128

Total final enrolment
1128

Key exclusion criteria
1. Patients younger than 60 years of age
2. Patients with a sub-trochanteric fracture
3. Patients who are managed non-operatively

Date of first enrolment
01/04/2016

Date of final enrolment
27/04/2018

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Industry

Funder Name
X-Bolt Direct Ltd

Results and Publications

Publication and dissemination plan

1. The lay member of the research team will lead dissemination to the patients and carers directly through their extensive network of patient advocacy organisations
2. Planned presentation of study results to the hip fracture clinical community at conferences, including the Annual meeting of the British Orthopaedic Association, the UK Orthopaedic Trauma Society
3. Planned publication in peer reviewed journals and social media
4. Patient reports will be made available to participants and the wider public

Intention to publish date
31/01/2021

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Xavier Griffin (Xavier.griffin@ndorms.ox.ac.uk).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	26/01/2018		Yes	No
Results article	results	01/02/2021	07/01/2021	Yes	No
HRA research summary			28/06/2023	No	No