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Warwick Hip Trauma Evaluation One

Submission date
19/12/2012

Recruitment status
No longer recruiting

Registration date
16/01/2013

Overall study status
Completed

Last Edited
02/06/2020

Condition category
Injury, Occupational Diseases, Poisoning

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Hip fractures are the most common osteoporotic fracture in the UK. They are the single greatest healthcare burden in this country. The best treatment of some types of these fractures remains controversial. Although there are several treatment options for this subtype of fracture, the current gold standard is the sliding (dynamic) hip screw. For this reason, this is the current default treatment for patients with this type of fracture enrolled in the WHiTE (Warwick Hip Trauma Evaluation) cohort study. A rate of complications and fixation failure in this subgroup remains high which has led to the development of implants such as the X-Bolt dynamic plating system. This system is very similar to a sliding hip screw, but differs in the nature of the fixation in the femoral head using a new type of expanding bolt. This may reduce the chances of the screw cutting out of the head and consequent failure of the fixation. We aim to explore the clinical effectiveness of this device compared to the sliding hip screw.

Who can participate?
Patients above 65 years of age, both those with and without capacity, presenting to University Hospital Coventry & Warwickshire NHS Trust with an AO / OTA type A2 and A3 fracture of the proximal femur.

What does the study involve?
Since this study will be embedded within the WHiTE cohort study we anticipate that the majority of participants will participate in both studies. The cohort study describes a common follow up regime the only additional element in this trial is the participants will be randomly allocated to one of two possible treatments (X Bolt Dynamic Plating System or Sliding Hip Screw of an eligible subset of patients with a specific hip fracture type. All patients will be asked to complete questionnaires at 1 month, 4 months and 1 year post injury. These questionnaires will be either completed via telephone interview or by return of post.

What are the possible benefits and risks of participating?
The X-Bolt dynamic plate fixation has potential mechanical advantages over the standard of care treatment of sliding hip screw. Patients enrolled in the study therefore have the chance of being allocated to a potentially superior treatment. The risks of the interventions are similar as both require operative fixation of the fracture. There is not thought to be an excess risk compared with normal clinical practice. There are no risks associated with the follow-up described for this study

Where is the study run from?
University Hospitals Coventry & Warwickshire NHS Trust

When is the study starting and how long is it expected to run for?
The study is expected to start in February 2013 and will run until February 2015.

Who is funding the study?
X-Bolt Direct Ltd

Who is the main contact?
Catherine Richmond
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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
WHiTE One/ Protocol/ 1.1

Study information

Scientific Title
Warwick Hip Trauma Evaluation One: a randomised controlled trial comparing sliding hip screw and X-bolt dynamic plate fixation in the treatment of unstable trochanteric fractures of the proximal femur

Acronym
WHiTE One

Study objectives
The aim of this trial is to investigate the clinical effectiveness of the X-bolt dynamic plating system compared with the sliding hip screw in the treatment of unstable trochanteric fractures of the proximal femur in terms of functional and health-related quality of life outcomes at one year following injury.

This randomised controlled trial will be embedded within the WHiTE Comprehensive Cohort Study registered under ISRCTN63982700.

Ethics approval required
Old ethics approval format

Ethics approval(s)
National Research Ethics Commitee West Midlands - Coventry & Warwickshire, 06/11/2012, ref: 12/WM/0352

Study design
Single centre multi-surgeon parallel two arm standard of care controlled randomised controlled trial

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 contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Proximal femoral fractures

Interventions
Intervention: X Bolt Dynamic Plating System
Control: Sliding Hip Screw

Average time taken per intervention/procedure:
Sliding hip screw fixation: 75 minutes
X-Blot dynamic plating system fixation: 75 minutes

Unstable trochanteric fractures (AO / OTA type A2/A3) are treated with fixation of the fracture in nearly all cases. This type of fracture is very unstable and as a result has a high incidence of complications, failure of fixation and reoperation.

The standard care for many years was the sliding hip screw which is successful in many cases. However, in some patients it does not offer enough stability for the fracture to heal, commonly the screws cut out of the femoral head necessitating revision surgery.

The X-Bolt dynamic plating system builds on the successful features of the sliding hip screw but aims to improve the fixation in the head by employing expanding flanges. These flanges compress the soft cellulous bone which is usually present in patients sustaining this type of fracture leading to a more secure fixation.

Intervention Type
Procedure/Surgery

Primary outcome measure
Observed differences in the EQ-5D score between the trial treatment goups at one year post-injury

Secondary outcome measures
1. Observed differences in the proportion of all cause revision surgery between trial treatment groups
2. Observed differences in the proportion of complications between the trial treatment groups

Overall study start date
01/02/2013

Completion date
01/02/2015

Eligibility

Key inclusion criteria
All patients (> 65 years, either sex) both with and without capacity, presenting to the University Hospitals Coventry and Warwickshire NHS Trust with an AO/OTA A2 and A3 fracture of the proximal femur

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
100

Total final enrolment
29

Key exclusion criteria

1. Patients younger than 65 years of age
2. Patients who are managed non operatively

Date of first enrolment
01/02/2013

Date of final enrolment
01/02/2015

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University Hospital Coventry and Warwickshire
Coventry
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Sponsor information

Organisation
University Hospital Coventry & Warwickshire (UK)

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Sponsor type
Hospital/treatment centre

Website
http://www.uhcw.nhs.uk/

ROR

https://ror.org/025n38288

Funder(s)

Funder type
Industry

Funder Name
X-Bolt Direct Ltd (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?
Protocol article	protocol	02/10/2013		Yes	No
Results article	results	01/05/2016		Yes	No
Results article	MoHIP sub-study results	22/05/2020	02/06/2020	Yes	No