World Hip Trauma Evaluation

Submission date	Recruitment status No longer recruiting	Prospectively registered		
13/12/2011		[X] Protocol		
Registration date	Overall study status Completed Condition category	Statistical analysis plan		
20/03/2012		[X] Results		
Last Edited		Individual participant data		
26/02/2021	Injury, Occupational Diseases, Poisoning			

Plain English summary of protocol

Background and study aims

Current as of 29/06/2017: This is cohort multiple embedded randomised controlled trial study. The study aims to capture data from the cohort of patients who present with a hip fracture at 21 NHS Trusts within the United Kingdom. We will record patient-reported outcomes and provide a baseline cohort within which to test the clinical effectiveness of experimental interventions through embedded randomised controlled trials.

Previous: The aim of this study is to evaluate the use of PROMs in the context of the National Hip Fracture Audit. It will record how well patients recover from their broken hip. The patients will be asked about their health using questionnaires in the post or over the telephone at 1 month, 4 months and 1 year.

Who can participate?

Current as of 29/06/2017: Patients presenting to one of the NHS Trusts with a fracture of the proximal femur.

Previous: Patients presenting with a fracture of the proximal femur to University Hospital Coventry & Warwickshire NHS Trust.

What does the study involve?

Current as of 29/06/2017: The study involves using patient reported questionnaires to monitor activity level, general health and how well they are able to perform certain day-to-day tasks at 4 months following a hip fracture.

Previous: The study involves using patient reported questionnaires to monitor activity level, general health and how well they are able to perform certain day-to-day tasks at 1 month, 4 months and 1 year following a hip fracture.

What are the possible benefits and risks of participating?

There are no specific benefits. There are no specific risks either. We will ask you to fill in some questionnaires. The information we get from this study may help us to treat future patients with hip fracture.

Where is the study run from?

Current as of 29/06/2017: The study is sponsored by the University of Oxford and is run from

Oxford Trauma, a part of the Nuffield Department of Orthopaedics Rheumatology and Musculoskeletal Sciences.

Previous: The study is run from University Hospitals Coventry & Warwickshire NHS Trust & University of Warwick.

When is the study starting and how long is it expected to run for? January 2011 to March 2023

Who is funding the study?
NIHR Programme Development Grants (UK)

Who is the main contact? Professor Matthew Costa white@ndorms.ox.ac.ik

Study website

https://www.ndorms.ox.ac.uk/research-groups/oxford-trauma

Contact information

Type(s)

Scientific

Contact name

Prof Matthew Costa

Contact details

Oxford Trauma
Kadoorie Centre
John Radcliffe Hospital
Oxford
United Kingdom
OX3 9DU
+44 1865 223111
white@ndorms.ox.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

-

Study information

Scientific Title

World Hip Trauma Evaluation: a comprehensive cohort study of patients with fracture of the proximal femur

Acronym

WHITE

Study objectives

NHS Trusts are required to follow-up and record data about all patients admitted with a fracture of the proximal femur as part of the National Hip Fracture Audit. This Audit records data relevant to service evaluation but does not contain patient-centred outcomes (PROMs). Therefore, it cannot provide meaningful data regarding the clinical effectiveness of treatments.

The aim of this study is to evaluate the use of PROMs in the context of the National Hip Fracture Audit.

Ethics approval required

Old ethics approval format

Ethics approval(s)

National Research Ethics Committee, London - Camberwell St Giles, 18/08/2011, ref: 11/LO/0927

Study design

Comprehensive cohort study

Primary study design

Observational

Secondary study design

Cohort study

Study setting(s)

Hospital

Study type(s)

Other

Participant information sheet

Not available in web format, please contact white@ndorms.ox.ac.uk to request a patient information sheet

Health condition(s) or problem(s) studied

Proximal femur fracture

Interventions

Patients will receive normal standard of care operative treatments for their proximal femur fracture. The type of operation will depend on their fracture classification.

- 1. Undisplaced intracapsular internal fixation
- 2. Displaced intracapsular -cemented hemiarthroplasty
- 3. Extracapsular and subtrochanteric internal fixation

Intervention Type

Procedure/Surgery

Primary outcome measure

Current outcome measures as of 29/06/2017:

EQ-5D measured at 120 days

Previous outcome measures:

EQ-5D measured at 1 month, 4 months and 1 year

Secondary outcome measures

Current secondary outcome measures as of 29/06/2017:

- 1. Mortality at 120 days
- 2. Complications at Baseline and 120 days
- 3. Residential Status at Baseline and 120 days
- 4. Mobility Status at Baseline and 120 days
- 5. Hospital information (Admission, assessment, treatment, discharge)
- 6. Resource Use at Baseline and 120 days

Previous secondary outcome measures:

- 1. ICEpop CAPability measure for Older people [ICECAP(O)] at 1 month, 4 months and 1 year
- 2. Oxford Hip Score at 1 month, 4 months and 1 year
- 3. Re-operation and cause
- 4. Length of index hospital stay

Overall study start date

01/01/2011

Completion date

01/03/2023

Eligibility

Key inclusion criteria

Participant inclusion criteria as of 21/09/2018:

Patients presenting with a fracture of the proximal femur to one of the participating sites

Previous participant inclusion criteria:

Patients presenting with a fracture of the proximal femur to University Hospital Coventry & Warwickshire NHS Trust

Participant type(s)

Patient

Age group

Senior

Sex

Both

Target number of participants

Sample size calculations will be undertaken for each of the embedded randomized controlled trials (RCTs), in the conventional manner. Details of sample size calculations for these embedded RCTs will be described in the relevant separate protocol for that research project.

Key exclusion criteria

- 1. Patients younger than 60 years of age
- 2. Patients who are managed non-operatively

Date of first enrolment

14/01/2012

Date of final enrolment

31/08/2022

Locations

Countries of recruitment

England

United Kingdom

Study participating centre Oxford Trauma

Kadoorie Centre John Radcliffe Hospital Oxford United Kingdom OX3 9DU

Sponsor information

Organisation

University of Oxford

Sponsor details

c/o Ms Heather House Head of Clinical Trials Research Governance Team Oxford England United Kingdom OX1 3BD +44 1865 572224 ctrg@admin.ox.ac.uk

Sponsor type

University/education

Website

https://www.ndorms.ox.ac.uk/research-groups/oxford-trauma

ROR

https://ror.org/052gg0110

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

Planned publication in a high-impact peer-reviewed journal.

Intention to publish date

01/06/2022

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	01/11/2012		Yes	No
Results article	results	21/10/2016		Yes	No
<u>Protocol article</u>	protocol for embedded pragmatic study	01/02/2021	26/02/2021	Yes	No