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World Hip Trauma Evaluation

Submission date
13/12/2011

Recruitment status
No longer recruiting

Registration date
20/03/2012

Overall study status
Completed

Last Edited
26/02/2021

Condition category
Injury, Occupational Diseases, Poisoning

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

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
Protocol article	protocol for embedded pragmatic study	01/02/2021	26/02/2021	Yes	No