

Long gamma nail versus sliding hip screw for the treatment of unstable pertrochanteric hip fractures

Submission date

26/03/2009

Recruitment status

No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date

07/04/2009

Overall study status

Completed

☐ Statistical analysis plan

☒ Results

Last Edited

07/04/2010

Condition category

Injury, Occupational Diseases, Poisoning

☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Mr Timothy Chesser

Contact details

Department of Trauma and Orthopaedics
Frenchay Hospital
Frenchay Park Road
Frenchay
Bristol
United Kingdom
BS16 1JE

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

A prospective randomised controlled trial comparing the long gamma nail with the sliding hip screw for the treatment of unstable pertrochanteric hip fractures

Study objectives

There is no difference in outcome between the sliding hip screw and the long gamma nail in the treatment of unstable pertrochanteric hip fractures.

Ethics approval required

Old ethics approval format

Ethics approval(s)

South West Local Research Ethics Committee approved on the 12th May 2003 (ref: Frenchay LREC/2003/20)

Study design

Single centre 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 the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Unstable pertrochanteric fractures of the proximal femur

Interventions

Patients entered into the trial were randomised to fixation of their proximal femoral fracture by either a sliding hip screw (Omega® II, Stryker, UK) or a long gamma nail (Dyax®, Stryker, UK).

Randomisation was via sealed envelopes. Neither participants nor physicians were blinded to treatment.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Re-operation within the first post-operative year.

Secondary outcome measures

1. Mortality in the first post-operative year
2. Requirement for a blood transfusion within one week of surgery
3. Length of hospital stay
4. Mobility and residency at one year
5. Euroqol EQ-5D at 3, 6 and 12 months post-operation

Overall study start date

01/04/2003

Completion date

01/04/2006

Eligibility

Key inclusion criteria

All patients (both males and females) over the age of 18 years admitted to the treating hospital with an unstable pertrochanteric hip fracture.

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

320

Key exclusion criteria

1. Pathological fractures
2. Previous proximal femoral fractures
3. Decision of the admitting physician

Date of first enrolment

01/04/2003

Date of final enrolment

01/04/2006

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Department of Trauma and Orthopaedics

Bristol

United Kingdom

BS16 1JE

Sponsor information

Organisation

North Bristol NHS Trust (UK)

Sponsor details

Frenchay Hospital

Frenchay Park Road

Frenchay

Bristol

England

United Kingdom

BS16 1JE

Sponsor type

Hospital/treatment centre

Website

<http://www.nbt.nhs.uk/>

ROR

<https://ror.org/036x6gt55>

Funder(s)

Funder type

Government

Funder Name

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?
Results article	results	01/04/2010		Yes	No