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

Submission date	Recruitment status
26/03/2009	No longer recruiting
Registration date	**Overall study status**
07/04/2009	Completed
Last Edited	**Condition category**
07/04/2010	Injury, Occupational Diseases, Poisoning

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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

North Bristol NHS Trust (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?
Results article	results	01/04/2010		Yes	No