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Scottish Trial of Arthroplasty or Reduction for Subcapital fractures (STARS)

Submission date	Recruitment status
25/04/2003	No longer recruiting
Registration date	**Overall study status**
25/04/2003	Completed
Last Edited	**Condition category**
10/07/2019	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

Study website
http://www.abdn.ac.uk/hsru/hta/stars.shtml

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
HTA 94/24/03

Study information

Scientific Title
Scottish Trial of Arthroplasty or Reduction for Subcapital fractures (STARS)

Acronym
STARS

Study objectives
In a prospective randomised multicentre trial we will evaluate the management of displaced subcapital fractures in fit elderly patients with bipolar hemiarthroplasty, total hip arthroplasty or reduction and fixation. The trial will be conducted under the auspices of the Scottish Orthopaedic Trial Network, which involves the four university orthopaedic centres and associated district general hospitals. Patients will be randomised to one of three treatment groups and will be followed up for a minimum of two years.

Please note that, as of 11/05/2009, the anticipated end date has been updated from 31/08/2000 to 31/08/2002.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration.

Study design
Prospective randomised multicentre trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

Participant information sheet

Health condition(s) or problem(s) studied
Injury, occupational diseases, poisoning: Musculoskeletal injury

Interventions
There are three treatment options:
1. One method of mending the break is with a type of screw, sometimes with a plate on its side; the two parts of the bone are joined together, and no bone is replaced.
2. A second method using a hip replacement. The ball at the end of the femur bone is replaced by an artificial 'ball' which is fixed into the top of the rest of the femur bone; the socket is not replaced.
3. The third method is also a type of hip replacement. Like the second method, the ball of the femur is replaced, but the socket in the hip bone is also replaced.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Clinical outcome will include perioperative mortality and reoperation. Functional outcomes will be assessed using a hip rating questionnaire and the EuroQoL functional outcome questionnaire. A cost-effectiveness and cost utility analysis will be integrated into the study protocol.

Secondary outcome measures
Not provided at time of registration.

Overall study start date
01/06/1996

Completion date
31/08/2002

Eligibility

Key inclusion criteria
Elderly patients with bipolar hemiarthroplasty, total hip arthroplasty or reduction and fixation.

Participant type(s)
Patient

Age group
Senior

Sex
Not Specified

Target number of participants
298

Total final enrolment
298

Key exclusion criteria
Not provided at time of registration.

Date of first enrolment
01/06/1996

Date of final enrolment
31/08/2002

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre
Department of Orthopaedics
Edinburgh
United Kingdom
EH16 4SU

Sponsor information

Organisation
Department of Health (UK)

Sponsor details
Quarry House
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Sponsor type
Government

Website
http://www.dh.gov.uk/en/index.htm

ROR
https://ror.org/03sbpja79

Funder(s)

Funder type
Government

Funder Name
NIHR Health Technology Assessment Programme - HTA (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	01/10/2005		Yes	No