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Optimum socket fixation at total hip replacement

Submission date	Recruitment status	[ ] Prospectively registered
12/09/2003	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
12/09/2003	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
16/04/2015	Surgery	[ ] Record updated in last year

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
N0203096528

Study information

Scientific Title
Optimum socket fixation at total hip replacement

Study objectives
For patients 65 and under the aim of this project is to show whether the use of cemented or uncemented sockets at total hip replacement confers the best clinical and radiological results. For older patients the aim is to establish which of two techniques of cementing the socket confers the best results. Patients will be divided into two groups on the basis of their age. Patients under the age of 65 will be randomised into a cemented or cementless group for socket fixation. Patients over 65 will have cemented sockets inserted using two long established techniques of cementing i.e. with or without a flange attached to the socket. Patients entering into the study will have tantulum markers inserted into the pelvis and prosthetic socket at the time of their hip replacement. The subsequent radiological follow-up will be carried out using the technique of Radiostereometry (RSA).

The study should show if there is any advantage in using expensive uncemented sockets in younger patients; the cemented arm of the trial should define whether the use of a flanged socket confers any advantage to a patient who has a cemented socket inserted. Roentgen Stereophotogrammetric Analysis (RSA) will detect early micromotion of the implants and will allow comparison of wear rates at the articulation. It may be possible to see at an early stage what sort of socket fixation is optimum.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Surgery: Total hip replacement

Interventions
A controlled, prospective trial to compare forms of socket fixation.

Randomisation:
Randomisation by sealed envelope in theatre into groups depending on age at surgery:
A. Patients 65 and under:
1. To have a cementless socket
2. To have a cemented socket
B. Patients aged 65 - 80:
1. To have cemented socket with flange attached to rim for pressurisation
2. To have identical cemented socket without flange attached to rim

Techniques and protocols:
All other surgical techniques and protocols will be identical between the groups and follow existing practice. All of the implants to be used are currently stocked at PEOC under existing NHS contracts. All surgical techniques to be used are universally accepted as contemporary practice.

Tantalum markers (0.8 mm or 1.0 mm) will be inserted into the rim of the socket and into the pelvic bone around the implant. Subsequent radiographs will be taken using a stereoradiographic method known as radiostereometric analysis (RSA) developed in 1974 by Goran Seivik. This method allows very accurate 3-dimensional measurements to be made from radiographs.

The tantalum balls have been inserted in at least 6000 patients over the past 30 years and no serious adverse reaction has ever been documented during or after insertion of the markers (Karrholm et al 1997).

The radiation dose from a radiographic examination is usually lower than the corresponding conventional one. In studies of the hip, radiation doses of 0.2-0.3 mSv have been calculated by Prof Karrhoim's group (10-20% of a conventional examination including anteroposterior (AP), lateral and pelvis view). The technique involves the use of higher kilovoltages and lower current from the X-ray generator thus reducing the dose of radiation to the patient.

Patients who have their operation on the Hip Unit at the Princess Elizabeth Orthopaedic Centre in Exeter are routinely X-rayed post-operatively and then reviewed at six weeks, six months and then at approximately three yearly intervals thereafter indefinitely. The group enrolled for this study will have additional reviews with X-rays at one year and two years. The films taken at each clinic attendance will be in place of the conventional series.

Intervention Type
Procedure/Surgery

Phase
Not Specified

Primary outcome measure
1. Life tables and Survival Curves with confidence limits for different definitions of failure including implant loosening and radiological evidence of failure including implant migration (as defined by RSA), excessive wear, radiolucencies etc.
2. Log rank comparison.

Secondary outcome measures
Not provided at time of registration

Overall study start date
30/11/1999

Completion date
30/11/2004

Eligibility

Key inclusion criteria
Any patient under 80 years of age undergoing primary total hip replacement at the Princess Elizabeth Orthopaedic Centre (PEOC) are eligible.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Not applicable

Key exclusion criteria
Patients refusing informed consent to the trial.

Date of first enrolment
30/11/1999

Date of final enrolment
30/11/2004

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Royal Devon & Exeter Hospital (Wonford)
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Sponsor information

Organisation
Department of Health (UK)

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Sponsor type
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Funder(s)

Funder type
Government

Funder Name
Royal Devon and Exeter 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