# Optimum socket fixation at total hip replacement

	Prospectively registered
No longer recruiting	Protocol
Overall study status	Statistical analysis plan
Completed	Results
Condition category	[] Individual participant data
Surgery	<ul><li>Record updated in last year</li></ul>
	Completed  Condition category

#### Plain English summary of protocol

Not provided at time of registration

## Contact information

#### Type(s)

Scientific

#### Contact name

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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)

Exeter, Devon United Kingdom EX2 5BW

# Sponsor information

#### Organisation

Department of Health (UK)

#### Sponsor details

Richmond House 79 Whitehall London United Kingdom SW1A 2NL

#### Sponsor type

Government

#### Website

http://www.doh.gov.uk

# 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