ISRCTN14542389 https://doi.org/10.1186/ISRCTN14542389

A radiostereometry assessment of bone graft in hip revision surgery

Submission date
06/08/2014

Recruitment status
No longer recruiting

Registration date
24/05/2016

Overall study status
Completed

Last Edited
18/10/2017

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
When hip replacements fail and have to be changed , there has usually been a significant amount of bone lost from around the implants. Often at the time of surgery, this lost bone is replaced with bone from a bone bank , where bone has been donated from patients who were undergoing hip replacement for the first time. Just like blood donation, the patients are screened for all known viral and prion (mad cow disease) infections before the bone is used. As with blood there remains a very small chance that new viruses or prions may be transmitted by the bone to patients. In order to increase the safety of the bone still further, a new means of sterilizing the bone to remove almost completely such a risk has been developed. The safety of the new bone and its mechanical properties in the laboratory has already been checked. As a final test, what happens to the bone in patients will be looked at using a special x-ray technique called radiostereometry. This technique of measuring whether the cup and bone graft move after they have been implanted can identify whether the bone is healthy and healing in place.

Who can participate?
Men and women aged between 50 and 80 who are having their hip replacements changed.

What does the study involve?
The two parts of the old hip replacement are removed. Bone is then be packed into the cup part (acetabulum) of the pelvis and a new cup cemented in place. The bone is chosen randomly immediately before the operation to be either the standard frozen bone or bone sterilized by the new method. The stem part of the hip replacement is then replaced and the hip put back into joint. During the operation, some tiny metal beads are placed into the two bones around the hip replacement. The beads are very small (less than 1mm across) and have been used to study joint replacements for almost 40 years. These beads allow medical staff to accurately identify the bone on radiostereometry radiographs. Radiostereometry radiographs are different from normal radiographs, in that two pictures are taken at the same time from different angles with a special cage holding the x-ray plates in position. Using special computer software, a three dimensional picture of the joint can be created with great accuracy. (This functions a bit like the 3D films seen in the cinema). The movement between the hip replacement and the beads in the bone are then measured, either when weight is put upon the leg or over time. The tiny movements seen can predict success or failure.

What are the possible benefits and risks of participating?
There is a slight increase in the amount of x-rays the patients receive. The study may benefit the patient were they to have any problems after surgery where the information collected would be given to the surgeon and might help in planning further treatment.

Where is the study run from?
Woodend Hospital, Aberdeen (UK)

When is the study starting and how long is it expected to run for?
September 2014 to October 2017

Who is funding the study?
Chief Scientists Office (Scotland)

Who is the main contact?
Mr George P Ashcroft
g.p.ashcroft@abdn.ac.uk

Contact information

Type(s)
Scientific

Contact name
Mr George Ashcroft

ORCID ID
http://orcid.org/0000-0002-5374-624X

Contact details
Polwarth Building
University of Aberdeen
Foresterhill
Aberdeen
United Kingdom
AB25 2ZD
-
g.p.ashcroft@abdn.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
3/015/13

Study information

Scientific Title
A radiostereometry assessment of bone graft processed with novel sterilisation techniques (a study of patients undergoing acetabular impaction grafting hip revision surgery).

Acronym
N/A

Study objectives
That chemical sterilisation used to reduce potential infection risk from allograft bone used in impaction grafting revision hip surgery will not alter the biological properties of the allograft. Hence graft incorporation and therefore migration over 2 years as measured by RSA will be the same as that for non processed bone.

Ethics approval required
Old ethics approval format

Ethics approval(s)
North of Scotland, 16/04/2013, ref: 13/NS/0029

Study design
Randomised, single centre, blinded

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 to request a patient information sheet.

Health condition(s) or problem(s) studied
Revision Hip replacement surgery

Interventions
A prospective study is being carried out on 50 patients undergoing impaction revision of the acetabulum for aseptic loosening of primary total hip replacement for osteoarthritis. Patients are randomised to impaction using standard fresh frozen allograft or processed bone.

Radiostereometry is used to measure the movement of the cup in terms of migration and rotation over a two year follow up period. Increased migration will imply poorer incorporation of bone graft and hence a significant change in either biological or mechanical properties.

Intervention Type

Phase
Not Applicable

Primary outcome measure
Migration and inducible movement of cemented acetabular components impacted. Each patient will be evaluated using standard weight bearing and non-weight bearing RSA radiographs at time of discharge, at six weeks, three months, six months, one year and two years after surgery. In addition, each patient will receive one repeat examination for clinical precision estimate in accordance with RSA guidelines.

Secondary outcome measures
1. Joint function, assessed using the Oxford Hip Score before surgery and again 12 months after surgery
2. General health,assessed using the Euroquol 5D score before surgery, 12 months after surgery and 24 months after surgery
3. Assessment of a hip arthroplasty via plain x-ray - radiolucency before surgery, just after surgery, then again at 12 months and 24 months

Overall study start date
20/09/2014

Completion date
01/10/2017

Eligibility

Key inclusion criteria
1. Age 50-80
2. First revision of cemented THR
3. Acetabular defects suitable for Impaction grafting

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
50

Key exclusion criteria
1. Previous surgery for inflammatory arthritis of the hip
2. Renal transplant or significant renal impairment
3. Immunosuppressive condition or recent high dose steroids
4. Known or suspected ipsilateral hip infection
5. Neurological disease limiting rehabilitation e.g. Parkinsons
6. Psychosocial disorders likely to limit rehabilitation
7. Geographical factors making follow up impractical
8. Other condition severely limiting life expectancy
9. Dementia or other condition affecting ability to give consent
10. Revision for periprosthetic fracture or dislocation
11. Facility for intraoperative exclusion (e.g. periprosthetic fracture, uncontained defect, suspected sepsis

Date of first enrolment
20/09/2014

Date of final enrolment
01/10/2017

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre
Polwarth Building
Aberdeen
United Kingdom
AB252ZD

Sponsor information

Organisation
University of Aberdeen / NHS Grampian (Scotland)

Sponsor details
R&D Office
Foresterhill House Annexe
Foresterhill
Aberdeen
Aberdeen
Scotland

United Kingdom
AB25 2ZB

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/016476m91

Funder(s)

Funder type
Government

Funder Name
Chief Scientists Office (Scotland) ETM/206

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date
01/10/2018

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?
HRA research summary			28/06/2023	No	No