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Cemented versus uncemented fixation of humeral components in total shoulder arthroplasty for primary osteoarthritis

Submission date
26/09/2005

Recruitment status
No longer recruiting

Registration date
26/09/2005

Overall study status
Completed

Last Edited
04/03/2009

Condition category
Musculoskeletal Diseases

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

Protocol serial number
UCT-48088

Study information

Scientific Title

Cemented versus uncemented fixation of humeral components in total shoulder arthroplasty for primary osteoarthritis: a randomised controlled trial

Study objectives
Our hypothesis is that uncemented fixation of the humerus will result in better disease-specific quality of life, decreased incidence of radiographic loosening, decrease operative time and no increase in complications.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Review Board for Health Sciences Research Involving Human Subjects in the University of Western Ontario gave approval on the 25th April 2001

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Primary osteoarthritis of the shoulder

Interventions
Group 1: Cemented fixation of the humeral component in total shoulder arthroplasty
Group 2: Uncemented fixation of the humeral component in total shoulder arthroplasty

Trial details received: 12 Sept 2005

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
The main evaluation of patient outcome is disease specific quality of life comparing the 2 groups at 2 years using several shoulder function rating scales. These include the Western Ontario Osteoarthritis of the Shoulder Index (WOOS), the Constant Score and American Shoulder and Elbow Surgeons (ASES) Standardised Shoulder Assessment form. Overall global health status will be measured and compared at 2 years using the Short Form-12 which has previously been shown to be the most appropriate instrument for evaluating global health status in orthopaedic clinical research.

Key secondary outcome(s)
The evaluation of radiolucent lines indicative of implant loosening and the incidence of revision surgery complications will be monitored during the 2 year post-operative course.

Completion date
30/04/2009

Eligibility

Key inclusion criteria
1. Primary osteoarthritis of the shoulder of grade III or higher (Kellgren and Lawrence modified for the shoulder)
2. Aged 18 years and older, either sex

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
Patients who have failed standard conservative management of their shoulder osteoarthritis

Date of first enrolment
01/04/2002

Date of final enrolment
30/04/2009

Locations

Countries of recruitment
Canada

Study participating centre
Fowler Kennedy Sport Medicine Clinic
London
Canada
N6A 3K7

Sponsor information

Organisation
The University of Western Ontario (Canada)

ROR
https://ror.org/02grkyz14

Funder(s)

Funder type
Research organisation

Funder Name
Canadian Institutes of Health Research (CIHR) (Canada) - http://www.cihr-irsc.gc.ca (ref: UCT-48088)

Funder Name
Zimmer (Canada)

Alternative Name(s)
Zimmer, Inc., Zimmer Biomet

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

Funder Name
Zimmer (USA)

Alternative Name(s)
Zimmer, Inc., Zimmer Biomet

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration