

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

Submission date 26/09/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 26/09/2005	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 04/03/2009	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

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

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

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

Not available in web format, please use the contact details below to request a patient information sheet

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 measure

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.

Secondary outcome measures

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.

Overall study start date

01/04/2002

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

160

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)

Sponsor details

Research Accounting, SLB, UWO

1151 Richmond Street North

London

Canada

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Sponsor type

University/education

Website

<http://www.uwo.ca/>

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

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