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

	Prospectively registered
No longer recruiting	☐ Protocol
Overall study status	Statistical analysis plan
Completed	☐ Results
Condition category	☐ Individual participant data
Musculoskeletal Diseases	Record updated in last year
	Completed  Condition category

# Plain English summary of protocol

Not provided at time of registration

# Contact information

# Type(s)

Scientific

#### Contact name

Dr Robert Bruce Litchfield

#### Contact details

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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

#### Study design

Randomised controlled trial

#### Primary study design

Interventional

# 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

Αll

#### 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**

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For-profit companies (industry)

#### Location

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# **Results and Publications**

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?

Participant information sheet
Participant information sheet
11/11/2025 No Yes