

Arthroscopic electrothermal capsulorrhaphy, ETAC, versus open capsular shift, ICS, for patients with shoulder instability: A multicentre randomized clinical trial

Submission date

09/09/2005

Recruitment status

No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date

09/09/2005

Overall study status

Completed

☐ Statistical analysis plan

☒ Results

Last Edited

31/01/2019

Condition category

Injury, Occupational Diseases, Poisoning

☐ Individual participant data

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

NCT00251160

Secondary identifying numbers

MCT-64671

Study information

Scientific Title

Electrothermal arthroscopic capsulorrhaphy: old technology, new evidence. A multicenter randomized clinical trial.

Study objectives

This is a superiority trial with a hypothesis that there is an improvement in quality of life in patients undergoing ETAC compared with the open ICS.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Faculty of Medicine, University of Calgary - 15th July 1999.

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Quality of life

Participant information sheet

Health condition(s) or problem(s) studied

Shoulder instability

Interventions

1. Open ICS (open capsular shift)
2. ETAC (Arthroscopic electrothermal capsulorrhaphy)

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Shoulder stability measured by the Western Ontario Shoulder Instability Index (WOSI)

Secondary outcome measures

1. Range of motion
2. Physical signs
3. Strength Instability

Overall study start date

01/09/1999

Completion date

30/09/2007

Eligibility

Key inclusion criteria

1. Age 14 years or greater, either sex
2. Diagnosis of Multidirectional Instability (MDI)
3. Informed written consent

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

58

Key exclusion criteria

1. Neurologic disorder (e.g. axillary nerve injury; Syringomyelia)
2. Cases involving third party compensation
3. Patients with primary posterior instability

Date of first enrolment

01/09/1999

Date of final enrolment

30/09/2007

Locations

Countries of recruitment

Canada

Study participating centre
University of Calgary
Calgary
Canada
T2N 1N4

Sponsor information

Organisation
University of Calgary (Canada)

Sponsor details
2500 University Drive N.W.
Calgary
Canada
T2N 1N4

Sponsor type
Not defined

ROR
<https://ror.org/03yjb2x39>

Funder(s)

Funder type
Research organisation

Funder Name
Canadian Institutes of Health Research (CIHR) (Canada) - <http://www.cihr-irsc.gc.ca> (ref: MCT-64671)

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/08/2014	31/01/2019	Yes	No