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

Submission date	Recruitment status No longer recruiting	Prospectively registered		
09/09/2005		☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
09/09/2005	Completed	[X] 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

ClinicalTrials.gov (NCT) NCT00251160

Protocol serial number

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

Study type(s)

Quality of life

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(s)

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

Key secondary outcome(s))

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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)

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

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