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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

Registration date
09/09/2005

Overall study status
Completed

Last Edited
31/01/2019

Condition category
Injury, Occupational Diseases, Poisoning

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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