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All-arthroscopic or mini-open repair of a rotator cuff tear

Submission date
05/06/2008

Recruitment status
No longer recruiting

Registration date
05/06/2008

Overall study status
Completed

Last Edited
08/06/2022

Condition category
Musculoskeletal Diseases

[_] Prospectively registered
[X] 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
NCT00128076

Secondary identifying numbers

MCT-82335

Study information

Scientific Title
All-arthroscopic versus mini-open repair of small or moderate sized rotator cuff tears: a randomised controlled trial using conventional and expertise-based designs

Acronym
MvA RCT

Study objectives
To compare the effectiveness of all-arthroscopic to mini-open rotator cuff repair to improve the quality of life, as measured by the Western Ontario Rotator Cuff (WORC) Index, in patients with a small or medium-sized rotator cuff tear.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Research Ethics Board of McMaster University approved on the 20th June 2006 (ref: 06-234)
2. Research Ethics Board of St. Josephs Healthcare approved on the 19th June 2006 (ref: 06-2680)
3. Office of Research Ethics of University of Western Ontario approved on the 8th May 2008 (ref: 12445)
4. Research Ethics Board of Sunnybrook & Womens College Health Science Centres approved on the 22nd January 2006 (ref: 082-2003)
5. Office of Medical Bioethics of University of Calgary approved on the 12th December 2005 (ref: 18559)
6. Health Research Ethics Board of University of Alberta approved on the 22nd June 2007 (ref: 6772)
7. Fraser Health Research Ethics Board approved on the 16th November 2007 (ref: FHREB 2006.062)

Study design
Multicentre, randomised, double blind (subject, outcomes assessor), parallel assignment, efficacy study

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
Shoulder pain, rotator cuff tear

Interventions
Mini-open rotator cuff repair surgery versus all-arthroscopic rotator cuff repair surgery.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Quality of life based on the validated self report assessment tool Western Ontario Rotator Cuff index (WORC), measured at baseline, at 6 weeks, 3, 6, 12, 18 and 24 months post-operatively.

Secondary outcome measures
1. Biological integrity of repair based on MRI, measured at baseline and 12 months post-operatively
2. Surgical complications monitoring, measured at baseline, at 6 weeks, 3, 6, 12, 18 and 24 months post-operatively
3. Adverse events reporting, measured at baseline, at 6 weeks, 3, 6, 12, 18 and 24 months post-operatively
4. Physical impairment assessments including:
4.1. Range of Motion (ROM) Assessment Scale, measured at baseline, at 6 weeks, 3, 6, 12, 18 and 24 months post-operatively
4.2. Strength (measured using a hand held dynamometer and scale), measured at baseline, at 6 weeks, 3, 6, 12, 18 and 24 months post-operatively
4.3. Composite Impairment Score, measured at baseline, at 6 weeks, 3, 6, 12, 18 and 24 months post-operatively
5. Pain/Disability: Shoulder Pain and Disability Index (SPADI) pain scale self report, measured at baseline, at 6 weeks, 3, 6, 12, 18 and 24 months post-operatively
6. General health: 12-item Short Form health survey (SF-12), measured at baseline, at 6 weeks, 3, 6, 12, 18 and 24 months post-operatively
7. Work limitations: measured using two self-report measures, measured at baseline, at 6 weeks, 3, 6, 12, 18 and 24 months post-operatively

Overall study start date
01/08/2006

Completion date
01/12/2010

Eligibility

Key inclusion criteria

1. Male or female patients
2. Aged 18 - 75 years
3. Small (0 - 1 cm) or moderate sized (1 - 3 cm) full-thickness rotator cuff tears of supraspinatus and infraspinatus, as determined by clinical examination and diagnostic imaging (magnetic resonance imaging [MRI]) prior to surgery

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
250

Key exclusion criteria
Pre-operative exclusion criteria:
1. Evidence of major joint trauma, infection, avascular necrosis, chronic dislocation, inflammatory or degenerative glenohumeral arthropathy, frozen shoulder or previous surgery of the affected shoulder
2. Evidence of significant cuff arthropathy with superior humeral translation and acromial erosion diagnosed by x-ray or other investigations
3. Major medical illness (life expectancy less then two years or unacceptably high operative risk)
4. Unable to speak or read English
5. Psychiatric illness that precludes informed consent
6. Unwilling to be followed for two years

Intra-operative exclusion criteria:
7. Large, massive, or irreparable cuff tears, extending into the subscapularis or teres minor which cannot be mobilised to the articular margin or repaired with both techniques
8. Teres minor or subscapularis tears
9. Inelastic and immobile tendon, which cannot be advanced to articular margin
10. Co-existing labral pathologies requiring repair with sutures (superior labrum anterior posterior [SLAP] II - IV), Bankart lesions requiring repair, partial tears of biceps (more than 60% of thickness) requiring tenodesis or release

MRI exclusion criteria:
11. History of head or eye injury involving metal fragments
12. Ever worked in a metal shop or been a soldier
13. Presence of implanted electrical device (such as a cardiac pacemaker)
14. Severe heart disease (including susceptibility to arrhythmias)
15. Metal braces on teeth
16. Pregnancy
17. Presence of intrauterine device

Date of first enrolment
01/08/2006

Date of final enrolment
01/12/2010

Locations

Countries of recruitment
Canada

Study participating centre
McMaster University
Hamilton, Ontario
Canada
L8S 1C7

Sponsor information

Organisation
McMaster University (Canada)

Sponsor details
1200 Main Street West
Hamilton, Ontario
Canada
L8N 3Z5

Sponsor type
University/education

Website
http://www.mcmaster.ca/

ROR
https://ror.org/02fa3aq29

Funder(s)

Funder type
Research organisation

Funder Name
Canadian Institutes of Health Research (CIHR) (Canada) - http://www.cihr-irsc.gc.ca (ref: MCT-82335)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	10/03/2006		Yes	No
Results article		01/10/2021	08/06/2022	Yes	No