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A randomized clinical trial comparing the effectiveness of rotator cuff repair with or without augmentation with porcine small intestine submucosa (SIS) for large rotator cuff tears: Pilot study phase

Submission date
05/09/2005

Recruitment status
No longer recruiting

Registration date
05/09/2005

Overall study status
Completed

Last Edited
12/04/2021

Condition category
Musculoskeletal Diseases

[ ] 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

Protocol serial number
MCT-63140

Study information

Scientific Title
A randomized clinical trial comparing the effectiveness of rotator cuff repair with or without augmentation with porcine small intestine submucosa (SIS) for large rotator cuff tears: Pilot study phase

Acronym
RESTORE

Study objectives
To compare the effectiveness of a standardized method of rotator cuff repair with or without augmentation using porcine small intestine submucosa (SIS) in patients with large rotator cuff tears.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the McMaster University Research Ethics Board on the 20th June 2003.

Study design
Randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Rotator cuff tears

Interventions
1. Standard open rotator cuff repair
2. Standard open rotator cuff repair augmented with porcine small intestine submucosa (RESTORE patch)

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)

Success or failure of the rotator cuff repair. Patients will undergo Magnetic Resonance Imaging (MRI) of the rotator cuff one year post-operatively to determine whether the defect has healed, and if not healed completely, whether the remaining full thickness defect is greater than 5 mm in any dimension. If such a defect remains, the patient is classified as having failed the repair.

Key secondary outcome(s))
1. The Western Ontario Rotator Cuff Index (WORC)
2. The American Shoulder and Elbow Surgeons standardized tool (ASES)
3. The Simple Shoulder Test (SST)
4. The Constant
5. The SF-36

Completion date
30/04/2007

Eligibility

Key inclusion criteria
Patients (18 - 65 years old, either sex) with large rotator cuff tears (Type 1B or Type 2) determined by clinical examination and diagnostic imaging. Criteria described by Harryman et al. (1991) will guide the classification of rotator cuff tears defined and reassessed at the time of surgery (Type 0 = intact cuff, Type 1A = thinned cuff or partial thickness defect, Type 1B = full thickness defect on one tendon, Type 2 = full thickness defect of two tendons, Type 3 = full thickness defect of three tendons).

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
62

Key exclusion criteria
1. Previous shoulder surgery, excluding acromioplasty or diagnostic arthroscopy
2. Inability of the surgeon to repair the tear with remaining defect no greater than 5 mm in diameter
3. Evidence of other significant shoulder pathology including, Type II-IV SLAP lesion, Bankart lesion

4. Active joint or systemic infection
5. Significant muscle paralysis of the shoulder girdle
6. Migration of the humeral head as demonstrated on plain radiograph
7. Major medical illness that would preclude undergoing surgery
8. Patients who are unwilling or unable to be assessed according to study protocol for one year following surgery
9. Major psychiatric illness, developmental handicap or inability to read and understand the English language

Date of first enrolment
01/09/2003

Date of final enrolment
30/04/2007

Locations

Countries of recruitment
Canada

Study participating centre
Clinical Epidemiology & Biostatistics
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Sponsor information

Organisation
McMaster University (Canada)

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-63140)

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		01/10/2016	12/04/2021	Yes	No