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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	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 05/09/2005	**Overall study status** Completed	
Last Edited 12/04/2021	**Condition category** Musculoskeletal Diseases	

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

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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 measure
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.

Secondary outcome measures
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

Overall study start date
01/09/2003

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
60

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
Hamilton
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Sponsor information

Organisation
McMaster University (Canada)

Sponsor details

Office of the Associate Dean
Research
McMaster University
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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-63140)

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