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The effect of an eccentric exercise program on patients with shoulder pain and disability, which is caused by dysfunction of the rotator cuff

Submission date
01/01/2014

Recruitment status
No longer recruiting

Registration date
11/03/2014

Overall study status
Completed

Last Edited
11/03/2014

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Shoulder pain is a very common complaint. Shoulder pain and stiffness has major effects on the use of healthcare resources and work-related costs. Exercise has been shown to help with many conditions, including tendinopathy. Tendinopathy is a term used to describe symptoms arising from a tendon (a tissue that connects muscle to bone). This study aims to find out the effect of a particular type of exercise on patients suffering from rotator cuff tendinopathy. This exercise is an eccentric exercise. Eccentric exercise is the lowering phase of an exercise, where your muscles are paying out, rather than contracting.

Who can participate?
Adult patients suffering from tendon-related shoulder pain can participate in this study.

What does the study involve?
Following assessment eligible patients who agree to participate will be randomly allocated to one of two groups. One of the groups will be treated using an eccentric exercise program, which will be demonstrated to them and conducted by the physiotherapist. They will also receive general advice. The other group will receive traditional physiotherapy treatment, including other forms of exercise and manual treatment techniques. All participants will be asked to complete various questionnaires at the beginning of the study, and at 6 and 12 weeks into their treatment .

What are the possible benefits and risks of participating?
Patients will not benefit directly from taking part in this study but the information we get may provide further knowledge about managing this condition. Participation in this study should be as safe as normal physiotherapy treatment.

Where is the study run from?
The study will be run from the Physiotherapy Department of St Vincents University Hospital, Dublin, Ireland.

When is study starting and how long is it expected to run for?
The study is expected to run from December 2013 until July 2014.

Who is funding the study?
Investigator initiated and funded (Ireland).

Who is the main contact?
Mr Micheal Bailey
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
The effect of an eccentric training program on patients clinically diagnosed with chronic unilateral rotator cuff tendinopathy

Study objectives
Tendinopathy is a generic term used to describe pathology in and pain arising from a tendon; it is associated with failed healing response, in this study we will be examining tendinopathy in relation to the rotator cuff tendons of the shoulder.

The aim of this study is to evaluate the effectiveness of a structured eccentric exercise program in the management of patients suffering from unilateral shoulder pain where rotator cuff tendinopathy is seen as the primary cause when compared with regular treatment.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethical Committee of St Vincent's University Hospital, 09/09/2013

Study design
Single blind randomized controlled trial

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
Rotator Cuff Tendinopathy

Interventions
Conservative management of rotator cuff tendinopathy using eccentric exercise.
Patients will complete 15 repetitions in three sets of each exercise twice a day. There are three exercises to complete. Patients will be provided with written and pictorial references as to the correct technique of these exercises and guided by the physiotherapist.

The control group will be treated with traditional physiotherapy intervention, excluding the above eccentric exercise program.

The duration of each participants involvement in the study will be 12 weeks. Measures will be taken at baseline, 6 weeks, and 12 weeks.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Pain and Disability - SPADI
2. Health Related Quality of Life - EuroQol EQ 5D

Outcomes measured at baseline, 6 weeks and 12 weeks

Secondary outcome measures
1. Shoulder Range of Motion - Goniometry assessed at baseline and end point
2. Patients perceived improvement - Global Rating of Change Scale assessed at 6 weeks and 12 weeks
3. Pain - VAS assessed at baseline and end point

Overall study start date
16/12/2013

Completion date
31/07/2014

Eligibility

Key inclusion criteria
1. Consent to participate
2. Male and female aged from 18 65
3. Sufficient range of motion (ROM) and function of non-affected shoulder ability to perform exercises
4. Shoulder pain which distributes pain over C4/5 dermatome
5. Passive range of shoulder movement which is greater than active range of movement
6. Pain which is reduced by rest
7. Pain on resisted external rotation or pain on resisted abduction
8. Symptom duration equal to or greater than 12 weeks

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
54 participants in each group. There will be two groups.

Key exclusion criteria
1. Recent shoulder/upper arm surgery
2. Recent shoulder or upper arm fracture
3. Recent shoulder dislocation

4. Symptoms aggravated by C-Spine range of movement
5. Severe resting pain
6. Signs of systemic/rheumatologic cause of symptoms
7. Obvious signs of cognitive impairment
8. Inability to understand written or spoken English
9. Bilateral symptoms which will impair participation in eccentric program
10. Positive Drop Arm

Date of first enrolment
16/12/2013

Date of final enrolment
31/07/2014

Locations

Countries of recruitment
Ireland

Study participating centre
Physiotherapy Department
Dublin
Ireland
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Sponsor information

Organisation
University College Dublin (Ireland)

Sponsor details
c/o Dr Cliona O Sullivan
School of Public Health, Physio & Pop Sc
Health Sciences Centre
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Ireland
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Sponsor type
University/education

Website
http://www.ucd.ie/

ROR
https://ror.org/05m7pjf47

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded (Ireland)

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