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The Efficacy of Acupuncture in Chronic Rotator Cuff Tendinitis

Submission date	Recruitment status	[ ] Prospectively registered
23/11/2009	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
18/03/2010	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
11/08/2011	Musculoskeletal Diseases	[ ] Record updated in last year

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
0.01

Study information

Scientific Title
The Efficacy of Acupuncture in Chronic Rotator Cuff Tendinitis: A Pilot Randomised Controlled Trial

Study objectives
Is acupuncture is an effective method of treating chronic rotator cuff tendinitis?

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Hamilton Health Science Research Ethics Board, McMaster University, Canada approved on the 26th of February 2010 (ref: 09-607)
2. Approval pending from the Institutional Review Board, Mayo Clinic, USA

Study design
Multicentre 3 arm randomised active and placebo controlled double blinded study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Chronic rotator cuff tendinitis

Interventions
After informed consent, patients will be randomised to one of three groups.
1. Traditional needle acupuncture
2. Laser acupuncture
3. Sham laser acupuncture

On the same day, these patients will have a history taken and a physical examination performed to exclude other causes of shoulder pain. Each patient will be examined by two independent physicians. Patients who meet the diagnostic criteria of rotator cuff tendinitis as assessed by the two physicians will be selected to enter the study. Disagreements between these two physicians will be resolved at the committee meeting. If the disagreement is not resolved, a third opinion by a qualified physician will be obtained. Other patients who do not meet the criteria will be excluded and referred to their family physician.
All subjects are then given education about Codman pendulum shoulder exercises to prevent potential shoulder stiffness. Patients are strongly encouraged to continue to take ibuprofen 200 to 600 mg every 6 hours or acetaminophen 320 to 500 mg every 4 hours on an as needed basis. These instructions will be given by one of the evaluating physicians.
The patients in all three groups will have ten sessions of metal needle, laser, or sham laser acupuncture treatments over a five week period by the same treating physician as described in the blinding section. Ten treatments are used because of previous systematic review suggests that this is the minimum number of treatments needed to produce sustained clinical effects.

Traditional Acupuncture Group:
Patients in this group will have needle insertion to a depth of 10-35 mm. The needle is then manually twirled for 30 seconds or until patients feel a dull pressure and warmth feeling around the needle (deqi). The treatment sessions will last 20 minutes with needles manipulated at the 10 minute mark.
Laser groups:
A research assistant not involved in the treatment or data analysis will enter the room prior to each laser intervention and flip the switch to either real treatment or placebo according to the group the patient has been randomly assigned to. The patient and the treating physician will be

blinded to this procedure and will enter the room only after the research assistant exits the area. The laser leads will then be applied to the same points used for the metal needle acupuncture group. The patient will remain hooked up to the machine for twenty minutes to produce 20 joules energy per point at 810 nm infrared laser.
The Shoulder Pain and Disability Index and the Oxford Analgesic Chart will be given before each treatment by the blinded research assistant. The assistants will also contact the patients at three and six months after completing their course of treatments. Each patient will keep a log of the amount of ibuprofen and acetaminophen used using the Oxford analgesic chart, which will be confirmed by the research assistant weekly. The patient will also fill out a form at the end of the treatment to document any adverse effects noted during treatment.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Physical function and pain status, assessed by the Shoulder Pain and Disability Index (SPADI) at baseline, 10 weeks (end of intervention) and 1 month post-intervention.

Key secondary outcome(s))
Amount of analgesics consumed, assessed by Oxford analgesic chart at baseline, 10 weeks (end of intervention) and 1 month post-intervention.

Completion date
30/06/2010

Eligibility

Key inclusion criteria
1. Age 18-70
2. Shoulder pain with abduction and aggravated by resistance testing (abduction, internal rotation, or external rotation)
3. Duration of pain ≥ 3 months
4. Willingness to travel to treatment centres and to be available for repeated follow-up phone calls

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
70 years

Sex
All

Key exclusion criteria
1. Receiving other modality of treatment aside from analgesics or non-steroidal anti-inflammatory drugs (NSAIDs)
2. Patients who have contraindication to NSAIDs such as ulcers or gastroesophageal bleeding
3. Unsettling legal or worker compensation claims

Date of first enrolment
02/01/2010

Date of final enrolment
30/06/2010

Locations

Countries of recruitment
Canada

United States of America

Study participating centre
Ancaster Sports Medicine Clinic
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Sponsor information

Organisation
Ancaster Sports Medicine Clinc (Canada)

Funder(s)

Funder type
Industry

Funder Name

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?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes