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Physiotherapy in management of mechanical shoulder pain

Submission date 07/06/2016	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 29/06/2016	**Overall study status** Completed	
Last Edited 30/11/2020	**Condition category** Signs and Symptoms	

Plain English summary of protocol

Background and study aims
Shoulder pain is a very common problem, which is often a complication of a disorder affecting the muscles in the shoulders. Treatment of long-term (chronic) should pain often involves physical therapy, using involving moving the shoulder joint around (manual therapy) and practicing exercises. Dry needling is a technique often used for pain management. It involves using either solid filiform needles (acupuncture needles) or hollow-core hypodermic needles to stimulate certain trigger points (myofacial trigger points) in the muscles to relieve pain. The aim of this study is to investigate the effectiveness of dry needling combined with manual therapy and therapeutic exercises in relieving pain and improving function in patients with chronic shoulder pain.

Who can participate?
Adults with long-term shoulder pain who have sensitive myofacial trigger points in their shoulder muscles.

What does the study involve?
Participants are randomly allocated to one of two groups who attend six study visits over six weeks. In the first study visit, patients either have dry needling, in which trigger points in their shoulders being treated with a filiform needle which is introduced through the skin into the muscle for 15 seconds, or sham needling, in which a sham (placebo) needle is used to prick the skin but not reach the muscle in the trigger points. For the remaining sessions, participants in both groups complete 75 minutes of manual therapy with a physiotherapist as well as practicing shoulder movement exercises twice a week for six weeks. Participants in both groups have their pain levels and shoulder function tested at the start of the study and then after one week, three months and six months.

What are the possible benefits and risks of participating?
There are no direct benefits or risks involved with participating in this study.

Where is the study run from?
Alcalá Clíinical University (Spain)

When is the study starting and how long is it expected to run for?
September 2015 to February 2017

Who is funding the study?
Alcalá University (Spain)

Who is the main contact?
Dr Daniel Pecos-Martin

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
CEIM/HU/2015/19

Study information

Scientific Title
Dry needling in a manual therapy protocol and therapeutic exercises for patients with chronic shoulder pain of unspecified origin

Study objectives
The application of deep dry needling in a manual therapy protocol and therapeutic exercises produces a significant improvement in the chronic shoulder pain of unspecified origin.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethical Comite of Alcalá University, 20/12/2015, ref: CEIM/HU/2015/19

Study design
Single-blind randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Shoulder pain of unspecified origin

Interventions
Participants are randomised to one of two treatment groups using Epidat 3.1 software.

Intervention group: Participants attend six study visits over a period of six weeks. In the first session, participants undergo Deep Dry Needling of the hyperalgesic points of infraspinatus muscle, upper trapezius, middle deltoid and subscapularis. This involves each muscle being treated with a filiform needle that will be introduced through the skin in order to eliminate pain. The technique is applied for 15 seconds on each muscle. For the remaining sessions, participants undergo 75 minutes of manual therapy, which involves practicing joint mobilization techniques in the glenohumeral joint, mobilization of the scapula, compression techniques and stretching of muscles.

Control group: Participants attend six study visits over a period of six weeks. In the first session, participants undergo Sham Dry Needling of the hyperalgesic points of infraspinatus muscle, upper trapezius, middle deltoid and subscapularis. his involves each muscle being treated with a placebo needle, i.e. the patient will feel pricking of the skin but the needle does not reach the muscle. For the remaining sessions, participants undergo 75 minutes of manual therapy, which involves practicing joint mobilization techniques in the glenohumeral joint, mobilization of the scapula, compression techniques and stretching of muscles.

Participants in both groups are asked to perform domiciliary Therapeutic Exercises twice a week, on non-consecutive days. These exercises involve active movement exercises without pain and stretching of muscles

Intervention Type
Procedure/Surgery

Primary outcome(s)
1. Functionality and quality of life is measured using the disabilities of the arm, shoulder and hand (DASH) scale at baseline, 1 week, 3 and 6 months
2. Pain is measured using a visual analogue scale (VAS) at baseline, 1 week, 3 and 6 months

Key secondary outcome(s))
1. Range of Motion (ROM) is measured using a goniometer at baseline, 1 week, 3 and 6 months
2. Medication intake is measured using interview at baseline, 1 week, 3 and 6 months
3. Pressure Pain Threshold (PPT) is measures using a algometer baseline, 1 week, 3 and 6 months

Completion date
15/06/2017

Eligibility

Key inclusion criteria
1. Aged 18 to 65 years
2. Chronic Shoulder Pain of Unspecified Origin (tendinitis, impingement syndrome, shoulder pain /painful shoulder) with a minimum of 3 months of pathology
3. Presence of active MTrPs or areas of hypersensitivity (upper trapezius, infraspinatus, middle deltoids and subscapularis)
4. Those who have Myofascial trigger points (MTrPs) that reproduce their pain in one or more muscles
5. Provision of informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
36

Key exclusion criteria
1. Participants who have undergone surgery on the shoulder, who suffered rotator cuff tear, adhesive capsulitis, calcific tendonitis, dislocation of the humeral head, shoulder instability, whiplash, cervical radiculopathy and previous interventions with corticosteroid injections
2. Associated pathologies, such as fear of needles, diabetes, osteoarthritis and fibromyalgia syndrome
3. Have received dry needling in the last six months
4. Receiving other physiotherapy treatment
5. Pregnancy

Date of first enrolment
16/09/2016

Date of final enrolment
16/02/2017

Locations

Countries of recruitment
Spain

Study participating centre
Alcalá Clíinical University
Faculty Physiotherapy
Crta Madrid - Barcelona, km 33. 600
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Sponsor information

Organisation
Alcalá University

ROR
https://ror.org/04pmn0e78

Funder(s)

Funder type
University/education

Funder Name
Alcalá University

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	18/09/2017	30/11/2020	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes