The clinical effect of enhancing adductor co-contraction in Subacromial Pain Syndrome. A prospective single-centre randomised controlled trial

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON55220

Source
ToetsingOnline

Brief title
CoCon trial

Condition

- Other condition
- Tendon, ligament and cartilage disorders

Synonym
chronic shoulder pain, SAPS, Subacromial pain syndrome

Health condition

Chronische schouderpijn

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Chronic shoulder pain, Co-contraction, Glenohumeral adductors, Subacromial Pain Syndrome (SAPS)

Outcome measures

Primary outcome

Clinical outcomes are pain (Visual Analogue Scale), arm-shoulder function

(Constant score).

Secondary outcome

Bio-physical-social health (RAND-36, Shoulder Rating Questionnaire) and,

self-reported quality of life (Western Ontario Rotator Cuff index).

Co-contraction as assessed with EMG will be expressed using the Activation

Ratio ([AR]; range [-1 to1]), indicating the task-related amount of antagonist

activation relative to the same muscle*s degree of agonistic activation,

corresponding to 1 in case of pure agonist muscle activation and -1 in case of

pure antagonistic activation. Furthermore, movement complexity and

proprioception, factors that potentially associate with the clinical course of

SAPS will be assessed using electromagnetic motion analysis (Flock of Birds,

FoB). Lastly, we will evaluate the content of care provided and compliance of

the patients by asking the patients to fill out a registration form on the

frequency, duration and content of treatment.

Study description

Background summary

In patients with Subacromial Pain Syndrome (SAPS), there is a potentially treatable muscle activation imbalance between arm abductors and arm adductors, that leads to the typical overloading of subacromial tissues during abduction. This muscular imbalance may result from declines in proprioception and/or movement complexity and can be restored with enhanced co-contraction. It has been recently shown that compared to age-matched controls, patients with SAPS have decreased co-contraction levels of arm adductors (humeral depressors) during abduction. Furthermore, it has been shown that an increase in adductor co-contraction associates with a favourable clinical course in patients with SAPS. Based on these findings and clinical observations, we propose that active enhancement of adductor co-contraction in patients with SAPS might be a beneficial treatment option.

Study objective

This study aims to assess if actively training adductor co-contraction in patients with SAPS is clinically effective. A specific therapy protocol is already in practice in the physical therapy department of the Leiden University Medical Center (LUMC). Secondly, we want to investigate if this clinical improvement is associated with increased co-contraction levels by electromyographic (EMG) assessment. Additionally, kinematic analysis will be performed in order to evaluate factors also associated with clinical outcome, including movement complexity and proprioception.

Study design

Randomised controlled trial with two study groups comparing the control group (standard care) with the inverventiongroup (standard care plus a specific physical therapy protocol aimed at enhancing adductor co-contraction).Clinical effect (questionnaires) and co-contraction of the Latissimus Dorsi, Teres Major, Pectoralis Major and/or Deltoid Muscle (electromyography, EMG) will be quantified in three study-related visits. The intervention period lasts 3 months and the effects will be monitored after 1 year.

Intervention

The patients will be randomly allocated to either the control (n=40) intervention group (n=40). All patients will receive standard-care treatment (information provided by the treating physician, relative rest and an ultrasound-guided subacromial corticosteroid injection). Additionally, the intervention group will receive specific *Scooping Therapy* treatment in the

LUMC. Scooping Therapy consists of a standardized physical therapy program with specific focus on active contribution of humeral-head depressors during abduction.

Study burden and risks

The intervention concerns specific scooping exercise therapy delivered by trained physical therapists from the LUMC according to a standardized protocol. There are no risks for participants. This study is embedded in standard treatment of SAPS and consists of three study-related visits to the Laboratorium for Kinematics and Neuromechanics. The assessments take approximately 2.5 hours in total. Completing the questionnaires, EMG- and FoB measurements may be inconvenient and burdensome. Data will be analysed according to the intention-to-treat principle.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

In order to participate in this study, a subject must meet all of the following criteria
- Chronic shoulder pain (>3months).
- Suspicion of subacromial origin of pain (e.g. combination of positive painful arc test, Hawkins-Kennedy test and empty can test).
- Presence of conventional ultrasonography.
- Presence of conventional radiographs.

Exclusion criteria

- Younger than 18 years of age;
- History of fracture or dislocation of the shoulder;
- History of surgery around the shoulder;
- Clinical and/or radiographic signs of comorbidities or alternative diagnoses of the affected shoulder (glenohumeral instability, glenohumeral/acromioclavicular osteoarthritis or arthritis, rheumatic disorder, history of trauma of the affected shoulder, capsulitis adhesiva, full thickness rotator cuff rupture, cervical radiculopathy, plexus lesions).
- Tendinitis calcarea >3mm, although part of saps; requires different treatment methods.
- Symptomatic cervical spine pathology;
- Neoplasms;
- Pregnancy;
- Cognitive impairment;
- Electronic implants (e.g. Implantable Cardioverter Defibrillator, pacemaker);
- Insufficient Dutch language skills;
- Refusing physical therapy treatment (for example, due to the absence of reimbursement);
- Refusing ultrasound guided subacromial corticosteroid injection;
- No informed consent.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel

Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	23-11-2020
Enrollment:	80
Type:	Actual

Ethics review

Approved WMO

Date:	05-12-2019
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	13-07-2020
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	02-06-2021
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL71012.058.19