Central pain sensitisation or (peri)articular damage: the origin of pain in SAPS
A randomised, placebo controlled, blinded, cross-over trial

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Ethical review	Approved WMO
Status	Will not start
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON47590

Source
ToetsingOnline

Brief title
PARTItrial

Condition

- Other condition
- Synovial and bursal disorders

Synonym
Painful Arc Syndrome, Subacromial Impingement Syndrome

Health condition

Chronische pijn in de schouder

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Reumafonds (SISTIM/ SUSY: P09.227). Aanvullende financiering (e.g. ZonMW;Reumafonds) wordt aangevraagd

Intervention

Keyword: Central pain sensitisation, Chronic pain, Etiology, Subacromial Pain Syndrome

Outcome measures

Primary outcome

Primary study paramaters are: 1) the effect of subacromial injections on pain

at rest and during abduction assessed with a visual analogue scale (VAS), 2)

CPS assessed with bilateral Quantitative Sensory Testing (QST).

Secondary outcome

Secondary study parameters (determinants) are two anchor questions for pain,

assessment of succesful blinded allocation, shoulder muscle activation ratios

(ARs), findings from ultrasonography, questionnaires and demographics and will

be used to assess factors that are associated with pain in SAPS.

Study description

Background summary

The Subacromial Pain Syndrome (SAPS), also known as the Subacromial Impingement Syndrome, is the most common shoulder disorder in primary health care, characterized by disabling chronic shoulder pain. With regards to the pathophysiology, several mechanisms have been suggested that generally share a focus on (peri)articular shoulder changes, e.g. the classic extrinsic, intrinsic and the dynamic mechanisms. Nevertheless, there is still a group of patients with symptoms that cannot be explained by (peri)articular changes

alone. We hypothesize that the explanation for the discrepancy between observed (peri)articular changes and the experienced pain in patients with SAPS, may be found in the processing of pain, i.e. central pain sensitisation (CPS).

Study objective

Our primary objective is to test the hypothesis that there is an association between high CPS at baseline and a low relative effect from subacromial anaesthetics (as compared to subacromial placebo). The increased pain perceived by these patients would rather originate from altered processing of pain, than from (peri)articular changes (alone).

Study design

A placebo controlled, blinded (patient, researcher, radiologist), randomised cross-over trial with two interventions (subacromial anaesthetics, placebo) that are uniform within sequence and within periods.

Intervention

In a randomised sequence, participants will receive two US-guided subacromial injections: one with anaesthetics (5cc lidocaine 1%, using a 50 mm 21 gauge needle) and one with a placebo (5cc NaCl 0.90%). There is a wash-out period of 1 week between both procedures.

Study burden and risks

Patients will be subjected to an US-guided subacromial injection with lidocaine and placebo. Such an injection (lidocaine) is often given in standard care for both diagnostic and therapeutic purposes. In 1-10% of lidocaine injections, paraesthesia, dizziness, bradycardia, hypotension, hypertension, nausea and vomiting are reported. Fulfilling three quality-of-life questionnaires can be burdensome and time consuming. Finally, QST measurements may be experienced as inconvenient. At completion of all study procedures, participants will receive a gift voucher of 40euros, in case of earlier drop-out 20 euros.

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

- Chronic shoulder pain (>3 months)
- Unilateral shoulder pain
- Suspicion of subacromial origin of pain (e.g. positive painful arc test, Hawkins-Kennedy test, empty can test)
- Presence of conventional ultrasonography
- Presence of conventional radiographs

Exclusion criteria

- Younger than 18 years of age
- Tendinitis calcarea
- Full thickness rotator cuff tear
- Suspicion of capsulitis adhesiva after clinical examination
- Glenohumeral osteoarthritis
- Medication that potentially act on central pain sensitisation (e.g. pregabalin, amitriptylin, duloxetine)
- Use of opioid analgesics, e.g. oxycodone.
- Suspicion of symptomatic acromioclavicular osteoarthritis (e.g. positive cross body adduction test)
- History of fractures or dislocations of the shoulder

- Cardiac disease
- Comorbidities: neurological disorders (e.g. plexus lesion), rheumatic disorders (e.g. polymyalgia rheumatic), muscle dystrophies, metabolic disorders (e.g. hypothyreodism), neoplasms
- Diagnosed with other chronic pain syndrome, e.g. diabetic polyneuropathy, chronic low back pain or fibromyalgia
- Insufficient Dutch language skills
- No informed consent

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	40
Type:	Anticipated

Ethics review

Approved WMO Date:	20-03-2017
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	23-08-2017

Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	05-04-2018
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	NL60408.058.16