The origin of pain in the Subacromial Pain Syndrome.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26751

Source
NTR

Brief title
PARTItrial

Health condition

Subacromial Pain Syndrome; Subacromial Impingement Syndrome; chronic shoulder pain.

Sponsors and support

Primary sponsor: Leiden University Medical Center (LUMC)
Source(s) of monetary or material Support: Leiden University Medical Center (LUMC), request for additional finance is pending.

Intervention

Outcome measures

Primary outcome

1) (peri)articular pain determined from effect of subacromial injections on pain at rest and during abduction assessed with a visual analogue scale (VAS), 2) pain sensitisation assessed with bilateral Quantitative Sensory Testing (QST), 3) shoulder muscle activation (expressed as Activation Ratios, ARs).

Secondary outcome

Secondary study parameters (determinants) are two anchor questions for pain, findings from ultrasonography, questionnaires and demographics.

Study description

Background summary

The Subacromial Pain Syndrome (SAPS) is the most common shoulder disorder in primary health care, for which 58/1000 persons seek medical help in the Netherlands yearly. SAPS is characterised by disabling shoulder pain that often results in ability to perform daily life activities and hence represents a great burden to our society (total costs per person within 6 months after first medical consultation: €689). With regards to the pathophysiology, several mechanisms have been suggested and these generally share a focus on (peri)articular changes leading to damage of subacromial tissue. Complaints often subside after treatment of damaged subacromial tissue, however, in up to 40% of patients, pain complaints become chronic. Especially in these patients, symptoms can often not be explained by (peri)articular changes, asking for better localisation of the origin of pain in SAPS. We aim to quantify the contribution of primary (peri)articular changes and secondary central sensitisation to pain, and to assess the role of altered muscle activation patterns, in SAPS. Three research questions will be addressed: 1) is high central pain sensitisation associated with a low effect of subacromial anaesthetics on pain?; 2) is there an effect of subacromial anaesthetics on central pain sensitisation?; 3) is there an association between central pain sensitisation and the effect of subacromial anaesthetics on muscle activation patterns?

Study objective

We hypothesise that in the Subacromial Pain Syndrome (SAPS), a differentiation between primary peripheral (i.e. (peri)articular) and secondary pain due to altered processing of pain, i.e. central pain sensitisation, is needed. We further hypothesise that patients who adapt their muscle activation may be less viable for central pain sensitisation. Knowing the different origins of pain may result in patient-specific treatment and improved outcome.

Study design

There are two visits at the LUMC with two moments per visit (a, b: 3-3,5 hours per visit). Visit 1a) informed consent, demographics, questionnaires (e.g. VAS for pain, Pain Catastrophizing Scale), bilateral QST by means of Temporal Summation and Conditioned Pain Modulation and ARs. Visit 1b) US-guided subacromial infiltration (lidocaine or placebo), VAS for pain, anchor question (pain), bilateral QST and ARs. Visit 2a) VAS for pain, ARs, bilateral QST, US-guided subacromial infiltration (lidocaine or placebo). Visit 2b) VAS for pain, anchor question (pain), bilateral QST, ARs.

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.

Contacts

Public
C.L. Overbeek
Leiden
The Netherlands
Scientific
C.L. Overbeek
Leiden
The Netherlands

Eligibility criteria

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

Recruitment

NL
Recruitment status: Recruiting

Start date (anticipated):	01-04-2017
Enrollment:	40
Type:	Anticipated

Ethics review

Positive opinion Date:	12-05-2017
Application type:	First submission

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
NTR-new	NL6259
NTR-old	NTR6433
Other	Medisch Ethische Toetsingscommissie (METC) van het Leids Universitair Medisch Centrum (LUMC) : P17.003

Study results