Manipulation under anesthesia versus conservative treatment in stage two of a frozen shoulder: a randomized controlled trial

No registrations found.

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

Summary

ID

NL-OMON21101

Source
NTR

Brief title
ConDoor - trial

Health condition

Frozen shoulder, adhesive capsulitis

Sponsors and support

Primary sponsor: none
Source(s) of monetary or material Support: none

Intervention

Outcome measures

Primary outcome

SPADI

Secondary outcome

OSS, NRS, EQ 5D, ROM, WORQ-UP

Study description

Background summary

Rationale: Frozen shoulder (adhesive capsulitis) is a common cause of shoulder pain and affects

approximately 2-4% of the general population. Idiopathic frozen shoulder is characterised by a

spontaneous onset of pain and stiffness of the shoulder, especially a loss in external rotation,

without a prior traumatic event. It is considered to be a self -limiting condition with a variable

duration of 1-3 years. However, this is a prolonged period with a considerable amount of pain and

disability in daily life. Traditionally, manipulation under anaesthesia is a well-established treatment

procedure for a frozen shoulder if conservative treatment fails. However, it is also a controversial

procedure because it might lead to complications as a fracture, dislocation or intra-articular injury.

The reported complication rate of manipulation under anaesthesia of 0.5% is rather low.

Nevertheless, we hypothesize that the course of the disease can be shortened with manipulation

under anaesthesia, potentially leading to a quicker functional recovery and gain in range of motion

compared to conservative treatment.

Objective: The current study aims to evaluate the difference in functional outcome, measured by the

SPADI, and the duration of symptoms, after treatment of a frozen shoulder with or without

manipulation under anaesthesia.

Study design: Randomized controlled trial

Study population: Adult patients with clinical signs and symptoms of a frozen shoulder in phase 2

presenting to the outpatient clinic of the department of orthopaedic surgery of the participating

hospital.

Intervention: Manipulation under anaesthesia

Main study parameters/endpoints: Primary outcome: Function, measured by the SPADI

Secondary outcomes: Function, measured by the oxford shoulder score (OSS). Pain at rest and during

activity (Numeric Pain Rating Scale). General health related quality of life (EQ-5D),Range of motion

(ROM), ability to work (Single item work ability Index, WORQ-UP in Dutch and Absenteeism past

month. Usage of analgesics. Number of repeated corticosteroid infiltrations.

Nature and extent of the burden and risks associated with participation, benefit and group

relatedness: Subjective scores to fill out, and an increased number of(non-invasive) measurements of

the function of the shoulder. Follow up consists of three moments at 1 month, 3 months and 1 year.

The benefit of the study is to provide an answer to the question if manipulation under anaesthesia

can indeed shorten the duration of symptoms and the advantages outweigh the possible

disadvantages. There is a minimal combined risk of approximately 0.5% during the manipulation.

possible complications of manipulation under anesthesia are: fracture, glenohumeral dislocation and

brachial plexus traction injury. Another risk is an overtreatment of patients with a mild / relatively

quick self-limiting natural course of the frozen shoulder.

Study objective

We hypothesize that the course of the disease can be shortened with MUA with a quicker functional recovery and gain in range of motion and a subsequent faster return to work compared to conservative treatment.

Study design

1, 3 months and 1 year

Intervention

Manipulation under anesthesia +

Physiotherapy

Contacts

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Eligibility criteria

Inclusion criteria

This study focusses on patients with a clinical diagnosis of a stage two FS. This is defined as symptoms of pain and stiffness, predominantly in one shoulder, persisting ≥ 3 months, without preliminary trauma which led to an anatomic abnormality. Characteristically, the pain is most severe at the end of the range of motion. Pain must be diminished compared to the maximum amount of pain in stage one of the condition.

In order to be eligible to participate in this trial, patients must meet all of the following criteria:

- Age □ 18 years and ≤ 70 years

- Restriction of passive motion in the glenohumeral joint of ≥30° in external rotation and at least a second plane of movement with ≥30°restriction (compared to the contra-lateral side)

- Unsuccessful conservative therapy within the previous 3 months

Exclusion criteria

If any of the following criteria will apply, patients will be excluded from participation:

- Numeric Pain Rating Scale at rest ≥ 7

- Onset of symptoms ≥ 1 year ago

- Osteoarthritis of the glenohumeral joint, Kellgren-Lawrence osteoarthritis grading scale ≥ 2

- Previous surgery to the shoulder

- Systemic inflammatory joint disease

- Evidence of a complete rotator cuff tear on physical examination, ultrasound images or MRI

- Neurological disorders of the upper limb

- Therapeutic anticoagulation which can not be interrupted without bridging therapy

- Other known shoulder pathology such as infection or tumor

- Contra-indication to corticosteroid injection, allergy to contrast or local anaesthetic

- Inability to give informed consent and fill out questionnaires

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-07-2017
Enrollment:	84
Type:	Anticipated

Ethics review

Positive opinion

Date:	15-01-2017
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	NL6043
NTR-old	NTR6182
CCMO	NL.56143.101.16

Study results