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Does subacromial injection influence shoulder strength?

Submission date	Recruitment status	[ ] Prospectively registered
13/04/2011	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
11/05/2011	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
11/05/2011	Musculoskeletal Diseases	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Does subacromial injection influence shoulder strength? A double blind placebo controlled study

Study objectives
1. Abduction strength is decreased after subacromial injection of a local anaesthetic (LA) with no radiographical guidance
2. Strength of the deltoid muscle and or supraspinate muscle is affected after blind subacromial injection of standard dose of a standard LA

Ethics approval required
Old ethics approval format

Ethics approval(s)
The study has been approved by the Ethical Committee of Kanton Zürich on 23rd December 2010

Study design
Double blind intra-indivudal placebo controlled single centre study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Subacromial injection for shoulder pain

Interventions
This study uses a double blind intra-indivudal placebo controlled design, where each shoulder that undergoes the intervention (subacromial injection of the local anesthetic) has an intra-individual control (the contralateral side) where placebo is applied.

For each of the 10 volunteers, the integrity of the supraspintus tendon is evaluated with ultrasonography on both sides. Only if no pathology is found on ultrasonography, the volunteer is included in the study. The abduction strength of both shoulders of the 10 healthy volunteers will be measured three times with Isobex (in 30° and 90° Abduction), while superficial electromyography (EMG) documents the activity of the deltoid muscle. Subsequently, randomly and blinded, 5ml 1% Lidocain in one shoulder and 5ml 0.9% saline solution in the contralateral shoulder will be injected without ultrasonographic guidance aimed to the subacromial space. The injection will be performed blindly because the technique is commonly used in daily clinic and the evidence is not conclusive, although however, might by trend favour the use of ultrasonographic-guided injections. The technique of the injection is based on commonly used

aseptic technique with a 21-gauge needle with the covered syringe, into the patients subacromial bursa via the anterolateral approach. Subsequently, the bilateral ultrasonography will be repeated to document the location of the injected fluid.

After 20min, again, the abduction strength of both shoulders will be quantified with Isobex (in 30° and 90° Abduction), while superficial EMG documents the activity of the deltoid muscle.

Neither the injecting physician nor the proband, nor who is measuring the abduction strength, will know which substance is injected.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Strength of shoulder abduction - Each volunteer undergoes an ultrasonography of both shoulders to assure full rotator cuff integrity then abduction strengths are measured. Subsequentely, either on the left or the right shoulder a local anaesthetic is injected. The other side serves as control, where sodium chloride (NaCL) is injected. Then we repeat the ultrasonography to document the location of the injected fluid and repeat the abduction strengths.

Secondary outcome measures
Radiographical documentation of location of the aimed subacromial injection

Overall study start date
30/04/2011

Completion date
30/04/2012

Eligibility

Key inclusion criteria
1. Past medical history not significant for major disorders
2. No shoulder pain
3. No previous operation or injections on the shoulder
4. No allergy to LA

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
10

Key exclusion criteria
Doe not meet inclusion criteria

Date of first enrolment
30/04/2011

Date of final enrolment
30/04/2012

Locations

Countries of recruitment
Switzerland

Study participating centre
Forchstrasse 340
Zürich
Switzerland
8008

Sponsor information

Organisation
Balgrist University Hospital (Switzerland)

Sponsor details
c/o Prof. C. Gerber
Forchstrasse 340
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Sponsor type
University/education

ROR
https://ror.org/02yzaka98

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Balgrist Universtiy Hospital (Switzerland)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration