Accuracy and effectiveness of posterior gleno humeral joint injection.

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Bone and joint therapeutic procedures
Study type	Observational non invasive

Summary

ID

NL-OMON39599

Source
ToetsingOnline

Brief title
Accuracy and effectiveness of gleno humeral joint injection.

Condition

- Bone and joint therapeutic procedures

Synonym
Capsulitis adhesiva, Frozen shoulder

Research involving
Human

Sponsors and support

Primary sponsor: Rijnland Ziekenhuis
Source(s) of monetary or material Support: Door de maatschap orthopaedie.

Intervention

Keyword: Capsulitis adhesiva, Corticosteroid, Gleno humeral joint, Intra articular injection

Outcome measures

Primary outcome

Questionaires:

- VAS (Visual Analoge Scale) Pain

- DASH (Disabilities of the Arm, Schoulder and Hand)

- SST (Simple Shoulder Test)

- Constant Murley Score

Injection corticosteroids/lidocaine/contrast:

An X-ray is made to see if the injection was placed intraarticular.

Secondary outcome

nvt

Study description

Background summary

Shoulder pain is a common complaint within the orthopedic practice. Intra-articular glenohumeral injections take an important place in the treatment and diagnosis of shoulder complaints. For diagnostic purposes, for example a MRI arthrogram, a contrast agent is used. As treatment the injection contains usually corticosteroids (Depomedrol) and an analgesic (Lidocaine). The main indications for intra-articular corticosteroid injections into the glenohumeral orthopedic practice are, capsulitis adhesiva or glenohumeral osteoarthritis.

There are several approaches for injection in the glenohumeral joint. The anterior and the posterior approach are the most common. In the Rijnland Hospital, all injections are given through the posterior approach.

There is little evidence about the accuracy of such injection. The anterior approach is most studied. In in-vivo studies, the results vary in accuracy of 26.8% to 96%. The posterior approach is less extensively studied. In the literature, the results of this approach vary from 15% to 85%.

In addition, there is little literature on the correlation between the accuracy and effectiveness of the glenohumeral injections. Hegedus-et-al showed no correlation in 103 patients with various shoulder pathology between positive results after a glenohumeral injection, and the accuracy or experience of the giver.

Study objective

The primary purpose of this study is to prospectively evaluate the accuracy of intra-articular glenohumeral injections via the posterior approach with (incipient) adhesiva capsulitis (frozen shoulder). Furthermore the confidence of the giver in a successful injection is tested.

The secondary objective is to demonstrate a relationship between the accuracy and effectiveness of intra-articular injections.

Study design

After the diagnosis capsulitis adhesiva is made on the outpatient clinic, the patient is enrolled. First they are asked to fill in the questionnaires, and an X-ray is made to check if there are no other underlying problems.
Then follows the injection via the posterior approach. All injections within this research are given by an experienced orthopedic surgeon with shoulder pathology as subspecialty. After the injection the surgeon evaluates (evaluation form (Appendix I)) if the intra-articular injection was placed successful.
At the Department of Radiology, a radiograph is taken to assess whether the contrast is actually injected intra-articular. The result is not communicated to the patient.
The patient will be, as usual, seen at the outpatient clinic 6 and 12 weeks after the injection. Then again the patient is requested to fill in the questionnaires. Should the appointment at 6 weeks again indicate an injection, the same procedure will be performed.
At the 12 week control moment the patient is announced if the contrast injections were intra-articular.

Radiography
After the injection, an AP shoulder x-ray** is made. On this radiograph we can distinguish whether the injection was intra-articular. An independent radiologist reviewes whether the injection was successfully placed intra-articular.

Study burden and risks

Allergic reaction from the contrast.

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

Intra-articular corticoid injection is indicated with capsulitis adhesiva.

Exclusion criteria

-Known allergic reaction on Depomedrol, Lidocaine or contrast.

-Clinical signs of full thickness rotatorcuff rupture.
-Clinical signs of infection.
-Within 6 weeks after rotatorcuff repair operation.
-Pregnancy.

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	07-04-2014
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO

Date:	02-09-2013
Application type:	First submission
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	NL42393.058.12