De effectiviteit van echografie in de huisartspraktijk: Het optimaliseren van de behandeling van patiënten met schouderpijn.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21348

Source
Nationaal Trial Register

Brief title
MUST

Health condition

Patients with shoulder pain in primary care

Sponsors and support

Primary sponsor: Dept. of General Practice, CAPHRI reserach school
Maastricht University
PO BOX 616
6200 MD Maastricht
The Netherlands

Source(s) of monetary or material Support: The ultrasounds are sponsored by:
MCC Omnes
Milaanstraat 100
6135 LH Sittard

Intervention

Outcome measures

Primary outcome

A 20% difference between study groups in patient-perceived recovery after 52 weeks.

Secondary outcome

1. Shoulder pain;

2. Performance of daily activities;

3. Health-related quality of life;

4. Cost-effectiveness.

Study description

Background summary

Background:

Subacromial disorders are considered to be the most common pathology affecting the shoulder. The optimal therapy for shoulder pain (SP) in primary care is yet unknown, since clinical history and physical examination do not provide decisive evidence as to the patho-anatomical origin of the symptoms, whereas this is needed to make adequate decisions regarding treatment. This can be solved by applying ultrasound imaging (US), an accurate method in diagnosing SP, having a clear relationship between diagnosis and therapies available. Yet, the cost-effectiveness of applying US in the management of SP in primary care has not been studied.

Objective(s)/ research question(s):

Optimizing the management of non-chronic SP in primary care by the introduction of US as a diagnostic triage tool. The following questions will be addressed:

1. What are the effects of diagnostic US and its related treatment decisions on clinical recovery and health-related quality of life compared to the usual primary care?

2. What is the cost-effectiveness of management that includes diagnostic US compared to the usual primary care?

3. What is the prevalence of the specific subacromial disorders?

Study design:

Randomized (at patient level) controlled trial, with a 52 week follow-up period.

Study population(s):

Patients aged between 18 and 65 years consulting the GP with a new episode of SP, suggestive for a subacromial disorder.

Intervention:

Therapeutic strategies used in both groups are the same except those used in the intervention group will be tailored based on the US results.

Outcome measures:

Primary outcome measures (patient-perceived recovery and all costs) and secondary outcome measures (shoulder pain, performance of daily activities, and health-related quality of life) will be assessed at baseline, and at 12, 26, 39 and 52 weeks after inclusion.

Sample size calculation/data analysis:

To detect a difference of 20% in patient-perceived recovery between the two groups, 226 patients have to be included. Study groups will be compared for their mean changes by an independent samples t-test and the Chi-square test.

Economic evaluation:

To determine the cost-effectiveness of US versus usual care, an economic evaluation will be performed from both a health care and societal perspective with a time horizon of 52 weeks.

Study objective

Subacromial disorders are considered to be the most common pathology affecting the shoulder. The optimal therapy for shoulder pain (SP) in primary care is yet unknown, since clinical history and physical examination do not provide decisive evidence as to the patho-anatomical origin of the symptoms, whereas this is needed to make adequate decisions regarding treatment. This can be solved by applying ultrasound imaging (US), an accurate method in diagnosing SP, having a clear relationship between diagnosis and therapies available. Yet, the cost-effectiveness of applying US in the management of SP in primary care has not been studied.

Study design

At baseline, demographic information will be collected including age, sex and profession, as well as disease specific information regarding the affected side, onset, duration of symptoms, possible cause of complaints, history of shoulder complaints, neck complaints and dominant arm.

The following outcome measures will be collected at baseline, 12, 26, and 52 weeks after inclusion:

1. Patient-perceived recovery: Global Perceived Effect questionnaire;

2. Shoulder pain: Shoulder Pain Score;

3. Performance of daily activities: Shoulder Disability Questionnaire;

4. Health-related quality of life: EQ-5D;

5. Cost-effectiveness: Cost questionnaire (additional questionnaire at 39 weeks).

Intervention

In a pragmatic design, which initially follows the guideline for shoulder pain of the Dutch College of General Practitioners, a study consisting of two phases will be carried out: a Qualification Period of two weeks followed by a randomised controlled trial with a 50 week follow-up period. The Qualification Period aims to filter out patients with a favorable natural course; this fits within the first line treatment as recommended in the guideline for shoulder pain of the Dutch College of General Practitioners. During this Qualification Period all patients are advised to start with paracetamol or NSAID in maximum dosage on a time contingent base, receive advice regarding activities of daily living, work, hobbies and sports, and they are referred for ultrasound of the shoulder to the radiology department of the Maastricht University Medical Centre (MUMC) or Orbis Medical Centre (OMC) in Sittard-Geleen, The Netherlands. Based on the qualification assessment at 2 weeks, patients with insufficient improvement qualify for the RCT. At that moment, these patients are randomly assigned to the intervention or the control group. The therapies used in both groups are the same except

that therapies used in the intervention group will be tailored based on the US results.
In the intervention group ultrasound of the shoulder will be used as a diagnostic triage tool to start tailored treatment:

1. Tendinopathy: Physiotherapy;

2. Bursitis: Corticosteroid injection;

3. Calcific tendinitis: Corticosteroid injection;

4. Partial-thickness tendon tear: Physiotherapy;

5. Full-thickness tendon tear: Referral to an othopedic surgeon.

In case pathology other than rotator cuff disorders is diagnosed, it will be treated according to this diagnosis (e.g. in cases of signs of rheumatoid arthritis patients are referred to a rheumatologist). If there is no detectable pathology, usual care according to the guideline for shoulder pain of the Dutch College of General Practitioners will be advised. In cases in which multiple ultrasound findings are present, the most relevant abnormality will be selected by the general practitioner on basis of the clinical findings. With an explanation, general practitioners are allowed to deviate from the advised treatments steps.

Usual care according to the guideline for shoulder pain of the Dutch College of General Practitioners will be applied in the control group. It consists of a pragmatic, stepwise approach; a wait-and-see policy with advice and analgesia for another 2 weeks; in persisting cases corticosteroid injections and referral to a physiotherapist are advised, depending on the level of pain and functional limitations respectively; referral to a hospital specialist is advised if conservative treatment fails.

Contacts

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Eligibility criteria

Inclusion criteria

Patients who visit their general practitioner with:

1. Shoulder pain upon abduction with painful arc;

2. Symptoms lasting no longer than three months;

3. First episode of SP for 12 months;

4. Men and women aged between 18 and 65 years.

Exclusion criteria

1. Consultation or treatment for SP in the past three months;

2. Glenohumeral external rotation range of motion less than 45 degrees;

3. History of fractures of the proximal humerus or acromion, dislocation and/or surgery of the affected shoulder;

4. Shoulder complaints caused by rheumatic disease, suspected referred complaints or extrinsic cause;

5. History of depressive or anxiety disorders, or pain catastrophising;

6. Inability to complete a questionnaire independently;

7. Unable to give informed consent (dementia or psychiatric disorders);

8. Involved in disability or liability procedures.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	04-10-2010
Enrollment:	226
Type:	Actual

Ethics review

Positive opinion

Date:	05-07-2010
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 38120
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL2277

Register	ID
NTR-old	NTR2403
CCMO	NL31681.068.10
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON38120

Study results

Summary results
N/A