

# Effectiveness of ultrasound imaging in general practice: optimising the management of patients with non-chronic shoulder complaints.

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To optimize the management of non-chronic shoulder pain in primary care by the introduction of ultrasound as a diagnostic triage tool. The following research questions will be addressed: 1. What are the effects of diagnostic ultrasound and its...

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Completed
<b>Health condition type</b>	Tendon, ligament and cartilage disorders
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON38120

### Source

ToetsingOnline

### Brief title

Maastricht Ultrasound Shoulder pain Trial (MUST)

### Condition

- Tendon, ligament and cartilage disorders

### Synonym

subacromial disorders and softtissue shoulder disorders

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Universiteit Maastricht

**Source(s) of monetary or material Support:** Ministerie van OC&W, De kosten voor echografie worden betaald door het Medisch Coördinatie Centrum Omnes (Diagnostisch centrum voor huisartsen in Sittard-Geleen).

## Intervention

**Keyword:** Management, RCT, Shoulder, Ultrasound

## Outcome measures

### Primary outcome

The primary outcome measures include patient-perceived recovery.

### Secondary outcome

The secondary outcome measures include shoulder pain, performance of daily activities, health-related quality of life, and costs.

## Study description

### Background summary

Shoulder pain presented in primary care results in a poor prognosis, considerable medical costs, and a prolonged sick leave. The optimal therapy for shoulder pain 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. Therefore, for all patients a stepwise treatment approach is advised. Unfortunately, this approach is expected to dilute the effects of the interventions in the total population considerably and delays specific therapy, which is remarkable knowing that a more effective approach to SP is available. Furthermore, in order to improve treatment outcome, a correct diagnosis at the earliest possible stage seems necessary. We hypothesize that this stepwise approach can be improved by giving the general practitioner (GP) more evidence as to patho-anatomical origin of the symptoms of SP. The diagnostic shortcoming can be solved by applying ultrasound imaging, an accurate method in diagnosing shoulder pain. Importantly, there is a clear relationship between ultrasound diagnosis and the available therapies. However, the cost-effectiveness of applying ultrasound in the management of shoulder pain in primary care has not been studied. This study foresees in the evidence gap that is addressed in the shoulder pain guideline of the Dutch College of General Practitioners.

## Study objective

To optimize the management of non-chronic shoulder pain in primary care by the introduction of ultrasound as a diagnostic triage tool. The following research questions will be addressed:

1. What are the effects of diagnostic ultrasound 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 ultrasound compared to the usual primary care?
3. What is the prevalence of the specific subacromial disorders?

## Study design

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

## Intervention

Ultrasound tailored treatment of shoulder pain. The therapeutic strategies available in the intervention and control group are identical except those used in the intervention group will be tailored based on the ultrasound results.

## Study burden and risks

One week after inclusion patients will receive a telephone call from the researcher of the dept of General Practice to answer the 1-item questionnaire regarding the complaints. All patients revisit their GP, but this visit is foreseen as it is part of usual care.

All randomised patients receive their therapeutic advice during this visit. No major risks will be associated with tailoring the therapeutic strategies to the ultrasound results, as these strategies are part of current practice. To prevent treatment of supposed asymptomatic pathology, ultrasound pathology will be linked to history and physical examination findings. In case a fracture, septic bursitis or arthritis, or a life-threatening disorder (e.g. tumour) is diagnosed, the radiologist will immediately inform the GP with c.c. to the investigator, and the patient will be excluded. Including baseline, patients are asked five times to fill in a questionnaire (takes ca. 5 minutes).

## Contacts

### Public

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## **Trial sites**

### **Listed location countries**

Netherlands

## **Eligibility criteria**

### **Age**

Adults (18-64 years)

Elderly (65 years and older)

### **Inclusion criteria**

- \* Referral by the GP to the radiology department for ultrasound of the shoulder;
- \* Shoulder pain upon abduction with painful arc;
- \* Symptoms lasting no longer than three months;
- \* First episode of shoulder pain for 12 months;
- \* Men and women aged between 18 and 65 years.

### **Exclusion criteria**

- \* Consultation or treatment for SP in the past three months;
- \* Glenohumeral external rotation range of motion less than 45 degrees;
- \* History of fractures of the proximal humerus or acromion, dislocation and/or surgery of the affected shoulder;
- \* Shoulder complaints caused by rheumatic disease, suspected referred complaints or extrinsic cause.

## Study design

### Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

### Recruitment

NL	
Recruitment status:	Completed
Start date (anticipated):	01-11-2010
Enrollment:	150
Type:	Actual

## Ethics review

Approved WMO	
Date:	23-07-2010
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO	
Date:	14-10-2010
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO	
Date:	11-08-2011
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Approved WMO	
Date:	18-10-2011
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO	
Date:	14-03-2012
Application type:	Amendment
Review commission:	MEC academisch ziekenhuis Maastricht/Universiteit Maastricht, MEC azM/UM (Maastricht)
Approved WMO	
Date:	05-04-2012
Application type:	Amendment
Review commission:	MEC academisch ziekenhuis Maastricht/Universiteit Maastricht, MEC azM/UM (Maastricht)
Approved WMO	
Date:	29-10-2012
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

## Study registrations

### Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 21348  
Source: NTR  
Title:

### In other registers

Register	ID
CCMO	NL31681.068.10
OMON	NL-OMON21348