

# Muscle elastography in neuromuscular disorders and connective tissue disorders

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Objectives in this study areBto investigate:1a.) the presence and distribution of fasciculations of muscle in Amyotrophic Lateral Sclerosis patients1b.) whether muscle elastography can be used as an early diagnostic tool in Amyotrophic Lateral...

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Pending
<b>Health condition type</b>	Musculoskeletal and connective tissue disorders NEC
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON30456

### Source

ToetsingOnline

### Brief title

Muscle elastography

### Condition

- Musculoskeletal and connective tissue disorders NEC

### Synonym

connective tissue disorders, muscle diseases

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Universitair Medisch Centrum Sint Radboud

**Source(s) of monetary or material Support:** Ministerie van OC&W,NWO subsidie (AGIKO)  
drs. N.C. Voermans

## Intervention

**Keyword:** connective tissue disorders, muscle elastography, muscle ultrasound, neuromuscular disorders

## Outcome measures

### Primary outcome

- 1.) average deformation of muscle belly in three directions
- 2.) local deformation of the muscle belly in three directions
- 3.) verloop in de tijd, de maximale waarde van de contractie, dan wel de tijd tot maximale contractie en relaxatie worden bepaald.

De bovenstaande elastografische parameters zullen worden gerelateerd met de aangebrachte stimulus, de gemeten kracht en de verschillende ziektebeelden.

De lokale vervorming van de spier. Ook deze parameter kan in 3 richtingen worden gemeten.

3. Van bovenstaande 2 parameters kan het verloop in de tijd, de maximale waarde van de contractie, dan wel de tijd tot maximale contractie en relaxatie worden bepaald.

De bovenstaande elastografische parameters zullen worden gerelateerd met de aangebrachte stimulus, de gemeten kracht en de verschillende ziektebeelden.

### Secondary outcome

not applicable

## Study description

### Background summary

Muscle ultrasound is a method to analyse muscle tissue quantitatively and

qualitatively in order to detect structural changes in muscle, which occur in several neuromuscular disorders. Our centre is currently investigating whether muscle ultrasound is a manner to differentiate various neuromuscular disorders. Elastography is a special ultrasound technique which can be used to detect movements and changes of shape. It is currently being used to detect the vulnerability of atherosclerotic plaques. We will combine these techniques and test the possibilities of muscle elastography. This offers dynamic perspectives which normal muscle ultrasound is lacking.

## **Study objective**

Objectives in this study are to investigate:

- 1a.) the presence and distribution of fasciculations of muscle in Amyotrophic Lateral Sclerosis patients
  - 1b.) whether muscle elastography can be used as an early diagnostic tool in Amyotrophic Lateral Sclerosis patients
  - 1c.) whether muscle elastography can be used as a predictor of disease progression in Amyotrophic Lateral Sclerosis patients
  - 1d.) whether muscle elastography can be used to differentiate Amyotrophic Lateral Sclerosis in an early stage from other neuromuscular disorders (e.g. inclusion body myositis)
- 2.) to investigate whether this technique can be used in (differential) diagnosis of other neuromuscular disorders.

## **Study design**

- 1.) pilot study on Amyotrophic Lateral Sclerosis patients
- 2.) elastography study on Amyotrophic Lateral Sclerosis patients, Ehlers-Danlos patients, inflammatory myopathy patients, and patients with a mitochondrial myopathy.

We refer to the protocol for an extensive description.

## **Study burden and risks**

not applicable

## **Contacts**

### **Public**

Universitair Medisch Centrum Sint Radboud

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6500 HB Nijmegen  
Nederland  
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## **Trial sites**

### **Listed location countries**

Netherlands

## **Eligibility criteria**

### **Age**

Adults (18-64 years)

Elderly (65 years and older)

### **Inclusion criteria**

- fulfilling the clinical criteria for above mentioned disorders  
We refer to page 8-10 of the protocol

### **Exclusion criteria**

- concomittant neuromuscular disorder
- diabetes mellitus
- lumbar radicular syndrome

We refer to page 8-10of the protocol

## **Study design**

## Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

**Primary purpose:** Basic science

## Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-07-2006
Enrollment:	40
Type:	Anticipated

## Ethics review

Approved WMO	
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

## 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	NL12573.091.07