# Unraveling the molecular and Cellular muscular mechanisms associated with Aging in rotator cuff Tears of the Shoulder

Published: 02-08-2013 Last updated: 18-07-2024

Identification of the molecular and cellular muscular mechanisms associated with aging in rotator cuff muscles with radiological quantification and clinical data.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Muscle disorders
Study type	Observational invasive

# Summary

### ID

NL-OMON41495

**Source** ToetsingOnline

Brief title CATS

### Condition

• Muscle disorders

**Synonym** rotator cuff tear

**Research involving** Human

### **Sponsors and support**

**Primary sponsor:** Leids Universitair Medisch Centrum **Source(s) of monetary or material Support:** Ministerie van OC&W,Rheumafonds

### Intervention

Keyword: Aging, Rotator cuff, shoudler, Tear

#### **Outcome measures**

#### **Primary outcome**

Growth capacity, Cell fusion, microarray (RNA)

#### Secondary outcome

MRI/CT quantification (pathology, fatty infiltration, muscle atrophy), Clinical

scores (Constant score, range of motion, muscle strength, VAS, DASH and WORC).

# **Study description**

#### **Background summary**

The ageing of skeletal muscles is associated with a progressive loss of cellular functions leading to an increasing muscle weakness. In the elderly, muscles may loose strength and become atrophic. Since shoulder mobility is primarily supported by the rotator cuff muscles, an aging-associated decline in muscle function could play a major role in the development and/or in the persistence of complaints of rotator cuff pathology. So far very little is known about aging-associated cellular and molecular defects in the rotator cuff.

#### **Study objective**

Identification of the molecular and cellular muscular mechanisms associated with aging in rotator cuff muscles with radiological quantification and clinical data.

#### Study design

Observational, cross sectional study.

#### Study burden and risks

Because all interventions we will apply are standard treatment of patients with symptomatic massive rotator cuff tear, risks and possible burdens are the same

as compared to the standard clinical situation. Only when the new MRI sequence (Dixon scan) is available, it will cost extra time for the patient. Muscle tissue samples will be within the operation area. No additional risk or burden is involved. No physiological discomfort during test administration is to be expected. The questionnaires, biomechanical measurements will cost extra time for the patient. Appointments are scheduled the same day as the appointments made at the outpatient clinic for usual healthcare.

# Contacts

**Public** Leids Universitair Medisch Centrum

Albinusdreef 2 Leiden 2333 ZA NL **Scientific** Leids Universitair Medisch Centrum

Albinusdreef 2 Leiden 2333 ZA NL

# **Trial sites**

### **Listed location countries**

Netherlands

# **Eligibility criteria**

Age Adults (18-64 years) Elderly (65 years and older)

### **Inclusion criteria**

Patients undergoing MRI/CT evaluation of the shoulder. For biopsies collection, MRI/CT proven shoulder pathology for which shoulder surgery is needed. These will include, but not be limited to:

- Shoulder instability (primary)
- Rotator cuff tearing
- Osteoarthritis
- Fractures

### **Exclusion criteria**

- Age < 18 and > 80 years
- No informed consent

- Comorbidity: neurological disorders (stroke, M. Parkinson, dementia, muscle disease), rheumatoid arthritis, polymyalgia rheumatic, heart failure, COPD (Gold III-IV), chronic pain syndrome (fibromyalgia, complex regional pain syndrome etc)

- Metabolic diseases (e.g. insuline dependent DM)
- Cancer

- Medication: immunosuppressive drugs (e.g. prednisone, methotrexat, biologicals (TNF-alpha antagonists etc))

- Limited access to obtain muscle biopsies due to surgical exposure.

# Study design

### Design

Study type: Observational invasive	
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

### Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	19-06-2014
Enrollment:	80
Туре:	Actual

# **Ethics review**

#### Approved WMO

Date: Application type: Review commission:	02-08-2013 First submission METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO	30-10-2013
Date:	Amendment
Application type:	METC Leiden-Den Haag-Delft (Leiden)
Review commission:	metc-ldd@lumc.nl
Approved WMO	16-09-2015
Date:	Amendment
Application type:	METC Leiden-Den Haag-Delft (Leiden)
Review commission:	metc-ldd@lumc.nl
Approved WMO	30-09-2015
Date:	Amendment
Application type:	METC Leiden-Den Haag-Delft (Leiden)
Review commission:	metc-ldd@lumc.nl
Approved WMO	10-11-2015
Date:	Amendment
Application type:	METC Leiden-Den Haag-Delft (Leiden)
Review commission:	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

ССМО

**ID** NL44516.058.13