

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, shoulder, 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

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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:

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- 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

Type: Actual

Ethics review

Approved WMO

Date: 02-08-2013
Application type: First submission
Review commission: METC Leiden-Den Haag-Delft (Leiden)
metc-ldd@lumc.nl

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

Approved WMO
Date: 30-09-2015
Application type: Amendment
Review commission: METC Leiden-Den Haag-Delft (Leiden)
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Approved WMO
Date: 10-11-2015
Application type: Amendment
Review commission: METC Leiden-Den Haag-Delft (Leiden)
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Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
CCMO	NL44516.058.13