# Physical activity and body composition in patients with Ankylosing Spondylitis

Published: 02-08-2007
Last updated: 08-05-2024

1) to investigate the occurrence and severity of muscle loss in patients with AS,2) to explore determinants of muscle loss,

| | |
|---|---|
| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Joint disorders |
| **Study type** | Observational invasive |

## Summary

### ID

NL-OMON30954

**Source**
ToetsingOnline

**Brief title**
Body composition in Ankylosing Spondylitis

### Condition

- Joint disorders

**Synonym**
Ankylosing Spondylitis

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Universiteit Maastricht
**Source(s) of monetary or material Support:** Ministerie van OC&W

### Intervention

**Keyword:** inflammation, muscle mass, physical activity

## Outcome measures

### Primary outcome

muscle mass (body compostition), physical activity, physical fitness, markers

of inflammation and muscle metabolism

### Secondary outcome

questionnaire assessed quality of life, disease activity, fatigue

# Study description

### Background summary

A healthy muscle mass is essential for daily life functioning. An accelerated loss of muscle mass is observed in the elderly (sarcopenia) and in chronic diseases such as chronic obstructive pulmonary disease (COPD) and rheumatoid arthritis (RA). In these chronic diseases, muscle loss is associated with reduced muscle strength, physical fitness, the ability to perform activities of daily life and hence quality of life, and is an independent predictor of mortality. Muscle loss can be caused by the pro-inflammatory cytokine tumour necrosis factor, especially TNF-* and by reduced physical activity. Ankylosing Spondylitis (AS) is a chronic inflammatory disorder of the spine and in a about 20% of patients of the peripheral joints, and causes functional limitations. TNF-* plays an essential role in the pathophysiology of the disease. Likley, these patients are at risk for muscle loss, which might contribute to their physical impairment and reduced quality of life.

### Study objective

1) to investigate the occurrence and severity of muscle loss in patients with AS,
2) to explore determinants of muscle loss,

### Study design

Patients with AS will be matched to age (5 years) and gender matched family members, preferably a brother or sister.

Body composition, including muscle mass, will be assessed using underwater weighing, deuterium dilution and magnetic resonance imaging (MRI). PA will be

monitored during daily life using an extensively validated tri-axial accelerometer. Fitness will be assessed using an incremental bicycle test and with a newly developed fitness index. Commonly used questionnaires for the assessment of quality of life and disease activity will be included and blood samples will be taken and analysed for TNF-*, C-reactive protein (CRP), erythrocyte sedimentation rate (ESR), the presence of the HLA B27 antigen, total cholesterol and triglycerides. A muscle biopsy will be taken (optional) to investigate local effects of TNF-* on the muscle. Biopsies will be analysed for muscle fibre type distribution and for molecular markers known to be involved in muscle cell differentiation and apoptosis (NF-*B, MyoD, Caspase).

### Study burden and risks

All techniques used for this study are non-invasive except for the blood sample and muscle biopsy. The biopsy is optional. Subjects can choose to participate without a muscle biopsy. The blood sample is part of standard medical treatment for the patients, but not for controls. All other techniques are of a very low risk and place little burden on the subject.

## Contacts

**Public**
Universiteit Maastricht

PB616
6200MD Maastricht
Nederland
**Scientific**
Universiteit Maastricht

PB616
6200MD Maastricht
Nederland

## Trial sites

### Listed location countries

Netherlands

# Eligibility criteria

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

## Inclusion criteria

Patients, between the age of 18 and 65, diagnosed with Ankylosing Spondylitis (AS) according to the New York Criteria for AS, with a BASDAI (Bath Ankylosing Spondylitis Disease Activity Index) >4, eligible for anti-TNF therapy according to the national guidelines.
Healthy controls: same gender, age within 5 years (and between 18 and 65) and family member of the respective patient.

## Exclusion criteria

Patients with other conditions known to affect energy metabolism (energy intake and/or expenditure) such as chronic inflammatory disorders (inflammatory bowel disease, COPD, rheumatoid arthritis,..), malignancies, AIDS, dieting will be excluded.
Controls will be excluded when any disorder known to affect energy metabolism is present (Ankylosing Spondylitis or any disorder listed above).
Subjects that meet any of the exclusion criteria for MRI (electronic implants, pacemakers, metal fragments in the eyes, skin or body) will be excluded.

# Study design

## Design

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

**Primary purpose:** Other

## Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 11-03-2008 |

| | |
|---|---|
| Enrollment: | 60 |
| Type: | Actual |

## Ethics review

| | |
|---|---|
| Approved WMO Date: | 02-08-2007 |
| Application type: | First submission |
| 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

No registrations found.

### In other registers

| Register | ID |
|---|---|
| CCMO | NL17118.068.07 |