

# Quantitative Chemical Shift Imaging of the lumbar spine in healthy volunteers

Published: 01-02-2012

Last updated: 27-04-2024

To determine the effect of ageing on bone marrow fat fraction as assessed by QCSI measurements

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruiting
<b>Health condition type</b>	Inborn errors of metabolism
<b>Study type</b>	Observational invasive

## Summary

### ID

NL-OMON35769

### Source

ToetsingOnline

### Brief title

QCSI measurements in healthy volunteers

### Condition

- Inborn errors of metabolism

### Synonym

Gaucher disease

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Academisch Medisch Centrum

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

### Intervention

**Keyword:** Bone marrow fat fraction, Gaucher disease, Quantitative Chemical Shift Imaging

## Outcome measures

### Primary outcome

The difference in bone marrow fat fraction, as assessed by QCSI, performed approximately 15 years ago versus today.

### Secondary outcome

NA

## Study description

### Background summary

Gaucher disease is one of the most common lysosomal storage disorders. The disease results from a deficiency of the lysosomal enzyme acid beta-glucocerebrosidase. The disorder is characterized by accumulation of macrophages filled with storage material in bone marrow, spleen and liver. Consequent signs and symptoms are organomegaly, cytopenia and bone complications.

The extent of bone marrow involvement in Gaucher disease can be measured by Dixon's Quantitative Chemical Shift Imaging (QCSI). This technique enables us to separate the total MR signal into the contributions made by fat and water and measures the relative contribution of the fat signal to the total signal. It has become a valuable tool in the follow up of Gaucher patients in the Academic Medical Centre of Amsterdam.

Bone marrow composition has been shown to be age-dependent, but the exact contribution of this factor to the bone marrow fat fraction as assessed by QCSI is yet unknown. A study by Ishijima et al suggests that bone marrow fat fraction increases in males between the ages of 5 and 34 and remains relatively stable thereafter. In women, bone marrow fat fraction is relatively stable between the ages of 5 and 44 and shows a rapid increase in women more than 45 years old. It is important to know the effect of age on QCSI results in order to enable a correct interpretation of the effect of treatment on bone marrow infiltration by Gaucher cells.

### Study objective

To determine the effect of ageing on bone marrow fat fraction as assessed by QCSI measurements

## Study design

This will be a follow up study to a previous reproducibility study in healthy volunteers (MEC 96/028).

## Study burden and risks

There are no significant risks associated with the intervention. The procedure will require approximately 30 minutes in the 1.5 Tesla MRI scanner. This is a non-invasive, non-ionizing imaging technique in which no contrast is used.

## Contacts

### Public

Academisch Medisch Centrum

Meibergdreef 9  
1105 AZ  
NL

### Scientific

Academisch Medisch Centrum

Meibergdreef 9  
1105 AZ  
NL

## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

## Inclusion criteria

Participation in the study \*Quantitative Chemical Shift Imaging van de lumbale wervels in gezonde vrijwilligers\* (MEC-nr. 96/028)

## Exclusion criteria

- Contra-indications for MRI scanning (using standard checklist, see appendix 4)
- A history of bone marrow pathology

## Study design

### Design

**Study type:** Observational invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Diagnostic

### Recruitment

NL

Recruitment status: Recruiting

Start date (anticipated): 04-10-2011

Enrollment: 16

Type: Actual

## Ethics review

Approved WMO

Application type: First submission

Review commission: METC Amsterdam UMC

## 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**

<b>Register</b>	<b>ID</b>
CCMO	NL35504.018.11