

# Diffusion-weighted magnetic resonance imaging (DW-MRI) as an imaging biomarker: reproducibility of measurements in liver and lung.

Published: 10-12-2012

Last updated: 26-04-2024

The aim of the present study is to measure the test-retest reproducibility of DW-MRI in healthy volunteers, in patients with colorectal liver metastases and in patients with malignant lung lesions in a multicenter setting.

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Metastases
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON39706

### Source

ToetsingOnline

### Brief title

DW-MRI

### Condition

- Metastases

### Synonym

Metastasis, neoplasma

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Universitair Medisch Centrum

**Source(s) of monetary or material Support:** IMI QuIC ConCePT (EU project)

## Intervention

**Keyword:** Diffusion, Imaging biomarker, MRI, Reproducibility

## Outcome measures

### Primary outcome

Reproducibility of apparent diffusion coefficient (ADC) measured with DW-MRI.

### Secondary outcome

n/a

## Study description

### Background summary

To detect changes in multiple diffusion-weighted magnetic resonance imaging (DW-MRI) scans in one patient, test-retest variability needs to be determined, to know when an observed difference is due to a true biological effect.

### Study objective

The aim of the present study is to measure the test-retest reproducibility of DW-MRI in healthy volunteers, in patients with colorectal liver metastases and in patients with malignant lung lesions in a multicenter setting.

### Study design

Prospective multicenter international observational study including 20 volunteers, 25 patients with colorectal liver metastases, and 25 patients with malignant lung lesions. All subjects will be scanned on two separate occasions (within one week), without intervening therapy. Personal characteristics will be registered (age, sex, bodyweight, height).

### Study burden and risks

n/a

## Contacts

### Public

Selecteer

de Boelelaan 1117 (4F11)  
Amsterdam 1081 HV  
NL

### Scientific

Selecteer

de Boelelaan 1117 (4F11)  
Amsterdam 1081 HV  
NL

## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

Volunteer study

- \* Age 30-50 or 60-80 years
- \* Able to remain supine for 30 minutes in the scanner
- \* Written informed consent

Patient study

- \* Age 18 years or older
- \* Colorectal liver metastases or lung metastases, or primary lung cancer (histological confirmation only in uncertain metastatic deposits)
- \* Minimum of one lesion > 2cm in diameter in liver or lung respectively
- \* Able to remain supine for 30 minutes in the scanner
- \* Written informed consent

## Exclusion criteria

- \* Contraindications for MRI
- \* Antitumor treatment targeted on the evaluable liver metastasis
- \* Antitumor treatment targeted less than 1 week prior to scan in malignant lung lesions
- \* Claustrophobia

## Study design

### Design

**Study type:** Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Diagnostic

### Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 20-02-2013

Enrollment: 14

Type: Actual

## Ethics review

Approved WMO

Date: 10-12-2012

Application type: First submission

Review commission: METC Amsterdam UMC

Approved WMO

Date: 08-03-2013

Application type: Amendment

Review commission: METC Amsterdam UMC

Approved WMO

Date: 31-07-2014

Application type: Amendment  
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

Register	ID
CCMO	NL41864.029.12