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

Published: 10-12-2012
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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.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Metastases
Study type	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

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Scientific
Selecteer

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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