Validation of diffusion weighted imaging in liver lesions

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Determine normal ADC values and the reproducibility of the ADC values in normal liver tissue and colorectal liver metastases in a multicentre trial. Determine the effect of lesion volume on reproducibility of the ADC values.

Ethical review	Approved WMO
Status	Pending
Health condition type	Malignant and unspecified neoplasms gastrointestinal NEC
Study type	Observational non invasive

Summary

ID

NL-OMON36935

Source
ToetsingOnline

Brief title
IMI-Quic DWI liver

Condition

- Malignant and unspecified neoplasms gastrointestinal NEC
- Hepatobiliary neoplasms malignant and unspecified

Synonym
colorectal livermatastases

Research involving
Human

Sponsors and support

Primary sponsor: European Organisation for Research in Treatment of Cancer (EORTC)
Source(s) of monetary or material Support: Innovative Medicines Initiative (partnership EU en EFPIA)

Intervention

Keyword: Diffusion weighted MRI, Liver

Outcome measures

Primary outcome

ADC values of normal liver, the liver metastases, the tumor volumes and the

reproducibility of the ADC values.

Secondary outcome

Not applicable

Study description

Background summary

Approximately 50% of primary colorectal cancers disseminates predominantly to the liver. Irresectable metastatic colorectal cancer is treated with systemic therapy. Since only 40%-60% of patients responds to this potentially toxic treatment, early response monitoring is desirable. Several studies have shown promising results for diffusion weighted imaging (DWI). Data on reproducibility are essential to ascertain the magnitude of changes detectable in the apparent diffusion coefficient (ADC). This is especially important for early response evaluation, since changes shortly after start of treatment may be small.

Study objective

Determine normal ADC values and the reproducibility of the ADC values in normal liver tissue and colorectal liver metastases in a multicentre trial. Determine the effect of lesion volume on reproducibility of the ADC values.

Study design

The livers of 5 healthy volunteers and 5 patients with colorectal liver metastases per participating centre will be scanned twice using DWI at 1.5T MRI (Siemens Avanto).

Study burden and risks

The risk associated with study participation are very low. No contrast agent is administered. No negative long term side effects of MRI are known to date. The study is not suited for claustrophobic patients/volunteers. No benefit for participants is to be expected. Burden: participants visit the clinic twice for 30-45 minutes to undergo both scans. For healthy volunteers and in lesser extent the patients there is a risk for unexpected findings.

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

Volunteers: 18 years and above.
Patients: at least one liver metastasis of histopathologically proven colorectal cancer

Exclusion criteria

Contra-indications for MRI: MRI-incompatible implants, pacemaker, claustrophobia;For patients: systemic treatment in the last 2 months prior to study participation

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-10-2012
Enrollment:	10
Type:	Anticipated

Ethics review

Approved WMO

Date:	06-12-2012
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL41968.091.12