

Development and in vivo testing of golden-angle radial sampling dynamic contrast-enhanced MRI (DCE-MRI) in combination with compressed sensing (CS) reconstruction

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To compare retrospectively reconstructed, radially sampled contrast-enhanced MR images of the liver with conventionally acquired contrast-enhanced MR images of the liver in terms of Quality of enhancement (QE), overall image quality (IQ), liver edge...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Hepatic and hepatobiliary disorders
Study type	Observational invasive

Summary

ID

NL-OMON50426

Source

ToetsingOnline

Brief title

DCERecon

Condition

- Hepatic and hepatobiliary disorders
- Synovial and bursal disorders

Synonym

hepatocellular carcinoma (HCC); liver cancer

Research involving

Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

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

Intervention

Keyword: Compressed sensing, Contrast agent, DCE-MRI, Radial

Outcome measures

Primary outcome

Quality of enhancement (QE), overall image quality (IQ), liver edge sharpness (HES), hepatic vessel clarity (HVC) and streak artefacts of (A) radially sampled contrast-enhanced MR images of the liver and (B) conventionally (clinical) acquired contrast-enhanced MR images of the liver scored by three experienced abdominal radiologists on a 5 points Likert-scale obtained in sub-study V.

Secondary outcome

Test-retest reproducibility of quantitative DCE-MRI parameters as derived from the retrospectively reconstructed, radially sampled contrast-enhanced MR images of the liver obtained in sub-studies IIIB and IV. Comparison of quantitative DCE-MRI parameters to diffusion-weighted images (IVIM) and MR elastography.

Study description

Background summary

Contrast-enhanced MR scanning plays an important role in the daily clinical diagnostic work-up of patients. In the abdomen, such scans can be compromised by respiratory motion artefacts and the impossibility to repeat a contrast agent administration bolus. New methods are being developed to overcome these hurdles and allow high quality images in free breathing. Golden-angle based

radial k-space sampling in combination with compressed sensing reconstruction have been shown to allow imaging in free breathing with high quality DCE images. The aim of this study is to (I) develop for Philips scanners in the AMC, (II) implement, (III) test golden-angle based radial k-space sampling in combination with compressed sensing reconstruction and (IV) compare contrast-enhanced images reconstructed using this method with conventionally acquired contrast-enhanced image sets. This should pave the way for these methods to become available for both clinical and research purposes in the AMC.

Study objective

To compare retrospectively reconstructed, radially sampled contrast-enhanced MR images of the liver with conventionally acquired contrast-enhanced MR images of the liver in terms of Quality of enhancement (QE), overall image quality (IQ), liver edge sharpness (HES), hepatic vessel clarity (HVC) and streak artefacts as assessed by three experienced abdominal radiologists

Study design

Prospective observational study.

Study burden and risks

Participating in this study leads to no immediate advantage for the individual participant. However, to be able to develop, implement and improve new contrast-enhanced MR applications, studies in healthy volunteers with contrast administration are mandatory. In the future, these newly developed MR methods are thought to be more patient-friendly and provide better image quality in comparison to the current methods.

The burden for subjects consists of either 1 × 30 minutes (20 healthy volunteers), 1 × 45 minutes (15 patients), 2 × 30 minutes (15 healthy volunteers) or 3 × 30 minutes (15 healthy volunteers) of extra MRI scan-time. Routine dosages of gadoterzour Gd-EOB-DTPA will be administered via an i.v. line. Adverse reactions to this type of contrast agent are rare. In the unlikely case of unexpected findings on the MR images (e.g. hitherto undiagnosed liver lesions), the general practitioner or treating consultant will be notified.

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

For healthy volunteers:

- * 18 years or older
- * Written, informed consent, For patients:
- * 18 years or older
- * Scheduled for clinical contrast-enhanced liver MRI
- * Written, informed consent

Exclusion criteria

For healthy volunteers and patients:

- * General contraindications for MRI (such as pregnancy and claustrophobia)
- * History of chronic renal insufficiency
- * History of allergic reaction to Gadolinium-containing compounds

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): 10-12-2015

Enrollment: 65

Type: Actual

Ethics review

Approved WMO

Date: 14-09-2015

Application type: First submission

Review commission: METC Amsterdam UMC

Approved WMO

Date: 21-12-2016

Application type: Amendment

Review commission: METC Amsterdam UMC

Approved WMO

Date: 28-03-2018

Application type: Amendment

Review commission: METC Amsterdam UMC

Approved WMO

Date: 16-10-2019

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	NL54247.018.15