Reproducibility of dynamic and diffusion weighted 3 Tesla MRI

Published: 20-05-2008
Last updated: 11-05-2024

To determine the reproducibility for quantitative analysis of MRI with contrast en diffusion weighted MRI (DWI) if abdominal malignant tumors.

Ethical review	Approved WMO
Status	Pending
Health condition type	Gastrointestinal neoplasms malignant and unspecified
Study type	Observational invasive

Summary

ID

NL-OMON32165

Source
ToetsingOnline

Brief title
UMCNONCO20071

Condition

- Gastrointestinal neoplasms malignant and unspecified

Synonym
abdominal tumor

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: DWI, dynamic MRI, MRI, Reproducibility

Outcome measures

Primary outcome

DCE-MRI: measure variables (Ktrans, VEE, kep, measured within a ROI),

DWI: ADC map

Secondary outcome

x

Study description

Background summary

In former research, we studied the characteristics of tumour vascularisation. We showed that the reproducibility of parameters measured by DCE-MRI can be improved by normalising the data with concentration-time graphs of the contrast medium Gadolinium in the supplying vains of the tumour (artery input function, AIF). In this method we determine the AIF for each DCE-MRI. This leads to a significant better reproducibility in brain tumours, prostate tumours and head and neck tumours. (3). A comparable analysis method has been applied to patientes with liver metastases. This resulted in good reproducibility data as well (4).

Above described research were perform,ed on a 1.5T MR scanner. Not much is known about the reproducibility techniques performed on a 3 T MR scanner. In general the signal/noise ratio increases with higher magnetic fields, which could lead to a better reproducibility of the data. However, the use of higher magnetic fields is also associated with a bigger chance of artifacts. The proposed research is designed to test the reprocucibility of the method of DCE-MRI contrast and DWI on our current clinical 3 T MR scanner.

In *Pilot study on the influence of Sunitinib on tumour vascularization and necrosis in patients with renal cell carcinoma* a dynamic contrast enhanced MRI (DCE-MRI) and diffusion weighted magnetic resonance imaging (DWI) takes place in the week prior to start with Sunitinib, and after tart op dag 3 en op dag 10. Deze MRI*s worden gemaakt om het effect van Sunitinib op vascularisatie van de tumor, het bloedvolume van de tumor en necrose in de tumor te bepalen. Hiertoe worden na de gebruikelijke conventionele anatomische beeldvorming diffusie gewogen beelden en T2* beelden opgenomen. Het MR contrast middel Gadolinium (Gd-DTPA) wordt intraveneus toegediend ten behoeve van het karakteriseren van tumor vasculatuur. Na een tweede intraveneuze bolusinjectie

van Gd-DTPA worden snelle T2* beelden opgenomen om het bloedvolume te bepalen. De onderzoeken vinden plaats op de klinische 3 T MR scanner. Voor een goede beoordeling van de data van deze lopende, reeds door het CMO goedgekeurde studie, zijn gegevens over de reproduceerbaarheid van belang.

Study objective

To determine the reproducibility for quantitative analysis of MRI with contrast en diffusion weighted MRI (DWI) if abdominal malignant tumors.

Study design

- 20 patients with an abdominal tumour of at least 2 cm diameters will be asked to participate
- Within one week a DCE-MRI and DWI (as described in the original protocol) will be performed twice
- The MRIs will be performed at least 24 hours after each other and maximum within a week, at the clinical 3T MR scanner
- Before the first DCE-MRI, a bloodsample will be taken to examine the liver enzyms (AST, ALT, alkalic phosphatase, gGT, LDH). Furthermore, a serum sample will be taken to examinen angiogentic facors.
- Each MRI takes about 45 minutes

Study burden and risks

The patient will undergo twice a MRI. There is a limited risk of allerguy to contrast, a haematoma. Furthermore, a very limted risk of contrast nephropathy exists.

Contacts

Public
Universitair Medisch Centrum Sint Radboud

P.O. Box 9101
6500 HB Nijmegen
NL
Scientific
Universitair Medisch Centrum Sint Radboud

P.O. Box 9101
6500 HB Nijmegen
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Patients with abdominal tumor of minimal size of 2 cm
Age > 18 years old
Signed informed consent

Exclusion criteria

Contraindication for MRI
Clinical condition not sufficient to lay down for 45 minutes to perform an MRI
Normal kidney function
No (prospective) liver transplant

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2008
Enrollment:	20
Type:	Anticipated

Ethics review

Approved WMO

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	NL20277.091.07