Implementation of diffusion weighted imaging in MRI pancreas

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Miscellaneous and site unspecified neoplasms benign
Study type	Observational non invasive

Summary

ID

NL-OMON37242

Source
ToetsingOnline

Brief title
Diffusion MRI pancreas

Condition

- Miscellaneous and site unspecified neoplasms benign

Synonym
cancer, RIP

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: Het UMC St Radboud stelt de MRI scan en begeleiding beschikbaar. Verder zijn er geen financiele middelen nodig.

Intervention

Keyword: Diffusion weighted imaging, MRI, Pancreas

Outcome measures

Primary outcome

Signal to noise ratio

Visual review by the investigators and the radiologist.

Secondary outcome

Not applicable

Study description

Background summary

Pancreas carcinoma has a bad 5-years survival, because late diagnosis. At the time of diagnosis, just 10% of all the patients can be operated for a curative threatment: a pancreas resection.
For that reason, it is very important that there will come a new method to diagnosis pancreas carcinoma.

Reason to develop an diffusion sequention for the pancreas protocol, is that a tumor is not distinguish from normal pancreas tissue or an infection, with CT or MRI.

Study objective

The objectuve of the study is to investigate the optimal geometry parameters and B-values by a acceptabel signal to nois ratio, for a diffusion sequention for MRI of the pancreas. It wil be investigate by a literature study and a practice study. The new protocol will be implementated in the current pancreas protocol for a 3T MRI at the medical centre UMC St Radboud. This investigation will be started in septembre 2012 and will be finished at january 2013

Study design

The new diffusion sequention will be take up in the current pancreas MRI protocol. The new diffusion protocol may be add 5 minutes at maximum to the total discoverytime. The new diffusion sequention will be investigate for a 3T

MRI. The diffusion protocol of the Liver will be taken as basic principle.
The first step is to discover geometry parameters and B-values in the literature study. After that, there will be a practice study. Both studys contribute to discover optimal geometry parameters and B-values by an acceptable signal to nois ratio.
The diffusionsequentie will be tested on healthy people.

Literature study:
- How looks a normal, healty pancreas on MRI?
- Which geometry parameters are important in a diffusion sequention of the pancreas?
- Which contrast parameters are important in a diffusion sequention of the pancreas?
- Which influence have some geometry parameters on the signal to noise ratio?
- Which B-values have to be chosen by a diffusion sequention of the pancreas?
- Which influence have the different B-values on the signal to nois ratio?

Practice study:
- Which geometry parameters, about which the literature has no clarity, do we have to chose for an acceptable signal to noise ratio for an optimal diffusion MRI image of the pancreas?
- Which contrast parameters, about which the literature has no clarity, do we have to chose for an acceptable signal to noise ratio for an optimal diffusion MRI image of the pancreas?
- Which ADC map gives the images by scanning the healthy people with certain B-values?
- Which B-values have to be chosen for an acceptable signal to noise ratio for an optimal diffusion MRI image of the pancreas?

Study burden and risks

The subjects have to come 1 time to medical centre UMC St Radboud for a MRI scan with a duration of 5 minutes. When it will be needed, the scan will be repeat for some times with a maximum time of 30-45 minutes even if the SAR value will be safe.

When the MRI scan will be used on a safety way, the risk for the subject is very low.
The investigators will be take care that there will be worked safe all the times.

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

Between 18-55 years old
Patient without pancreas pathology
Healthy
Men and woman

Exclusion criteria

Patient with pancreaspathology: diabetic, chronic or acute pancreatic disease, benigne or maligne tumor of the pancreas.
Scared in small spaces
Pregnant

Pacemaker, artifical heart valve, recent operation
Person who can not lay down for 30 minutes
Person who can not lay horizontal

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):	01-09-2012
Enrollment:	5
Type:	Anticipated

Ethics review

Approved WMO

Date:	28-09-2012
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	NL41511.091.12