Functional magnetic resonance imaging of pancreatic cancer: a feasibility and reproducibility study

Published: 21-09-2012
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To optimize DCE-MRI, T2* MRI and DWI in pancreatic cancer at 3T and investigate its reproducibility.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Hepatobiliary neoplasms malignant and unspecified
Study type	Observational invasive

Summary

ID

NL-OMON41555

Source
ToetsingOnline

Brief title
MRI of pancreatic cancer

Condition

- Hepatobiliary neoplasms malignant and unspecified

Synonym
pancreatic 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: MRI, optimalization, pancreatic cancer, reproducibility

Outcome measures

Primary outcome

Reproducibility of MRI parameters.

Secondary outcome

Correlation of MRI parameters with histology.

Study description

Background summary

Novel predictive markers are needed to determine treatment efficacy in pancreatic cancer at an early stage. Preferably, these markers could be determined non-invasively and provide insight into the biology of pancreatic cancer. Several MR techniques can serve for this purpose. However, optimalisation of these techniques is needed and their reproducibility should be assessed.

Study objective

To optimize DCE-MRI, T2* MRI and DWI in pancreatic cancer at 3T and investigate its reproducibility.

Study design

In the first part of the study, patients with pancreatic cancer will undergo an MR measurement protocol once at 3T, to optimize MR techniques (DCE-MRI, T2* MRI and DWI). In the second part of the study, to assess reproducibility patients will undergo the MR measurement protocol twice within one week before start of any treatment.

Study burden and risks

Participation mainly concerns a time investment (60 min for the optimalisation part of the study and 2x45 min for the reproducibility part of the study). Administration of contrast agent is associated with a small risk on an allergic

reaction. Administration of Buscopan may cause adverse effects.

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

* Patients with pancreatic tumors, with histological or cytological proof of adenocarcinoma or a high suspicion on CT imaging.
* Any tumor with a size * 1cm
* WHO-performance score 0-2
* Written informed consent

Exclusion criteria

* Any psychological, familial, sociological or geographical condition potentially hampering adequate informed consent or compliance with the study protocol.
* Contra-indications for MR scanning, including patients with a pacemaker, cochlear implant or neurostimulator; patients with non-MR compatible metallic implants in their eye, spine, thorax or abdomen; or an aneurysm clip in their brain; patients with severe claustrophobia.
* Renal failure (GFR < 60 ml/min) hampering safe administration of a double bolus of Gadolinium containing MR contrast agent.
* For the reproducibility part of the protocol: surgery, radiation and/or chemotherapy foreseen within the timeframe needed for MRI scanning.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	10-04-2013
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO Date:	21-09-2012
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	08-09-2014

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	NL40501.018.12