Preoperative detection of lymph node metastases in pancreatic and periampullary carcinoma using ultrasmall super paramagnetic iron oxide nanoparticle ferumoxtran-10.

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Exocrine pancreas conditions
Study type	Observational invasive

Summary

ID

NL-OMON47341

Source
ToetsingOnline

Brief title
3T Nano-MRI: a feasibility study in pancreatic and periampullary carcinoma

Condition

- Exocrine pancreas conditions

Synonym
Pancreas carcinoma and periampullary carcinoma

Research involving
Human

Sponsors and support

Primary sponsor: Radiologie en nucleaire geneeskunde
Source(s) of monetary or material Support: donatie

Intervention

Keyword: Cancer, Ferumoxtran-10, Pancreas, USPIO-MRI

Outcome measures

Primary outcome

Sensitivity and specificity both on a regional level and on a patient level of

the 3T MRI scan with USPIO contrast agent for detecting lymph node metastases

in pancreatic and periampullary cancer.

Secondary outcome

Sensitivity and specificity both on a lesion level and on a patient level of

the 3T MRI scan with USPIO contrast agent for detecting liver metastases in

pancreatic and periampullary cancer.

Delineation of the tumor on USPIO-MRI compared to contrast-enhanced CT.

Detection of tumor associated macophages in a pancreatic and periampullary

carcinoma.

Study description

Background summary

Pancreatic ductal adenocarcinoma (PDA) is a devastating disease with a dismal prognosis which has not improved substantially in the past 40 years. A good preoperative TNM staging is of importance to determine the appropiate therapy and prognosis. An important negative prognostic factor is the presence of para-aortic lymph node metastases which are regarded as distant metastases and therefore precludes a curative resection of the tumor.
In only 33% of cases para-aortic lymph node metastases are detected

preoperatively, due to the low sensitivity of CT and conventional MRI. Moreover, after a curative resection in 70% of patients liver metastases or a local recurrence of disease occurs usually in the lymph nodes of the mesenteric root and in the para-aortic lymph nodes. This suggests that at the time of surgery micrometastases in the liver and lymph nodes were already present. Determining lymph node status preoperatively, however, is a challenge. Ferumoxtran-10, an ultrasmall superparamagnetic iron oxide (USPIO) particle has proven to be a valuable contrast agent for detecting lymph node metastases using magnetic resonance imaging (MRI) in various types of cancer (also called nano-MRI). With this study we would like to validate the results of this technique with pathology in patients with pancreatic and periampullary cancer. Ultimately improved preoperative staging of pancreatic and periampullary cancer leads to an improved treatment stratification plan. Demonstration of para-aortic lymph nodes could prevent an unnecessay operation with its associated morbidity and mortality and therefore improve quality of life. Additionally, if metastatic lymph nodes are present, it could complement image guided focal therapies on lymph node metastases such as radiotherapy and electroporesis.

Study objective

The first objective is to improve preoperative staging with 3T NANO-MRI regarding the detection of lymph node metastases in patients with a pancreatic or periampullary carcinoma when compared to a conventional contrast-enhanced CT or MRI. Other objectives are to improve a) the detection of liver metastases, b) the delineation of the tumor and c) the determination of local vessel ingrowth by the tumor.
A more fundamentally oriented objective aims to detect "tumor associated macrophages" in a pancreatic or periampullary carcinoma with an in vivo 3T NANO-MRI.

Study design

Feasibility study.

Study burden and risks

Except for the discomfort of lying in an MRI scanner for about 1 hour, MRI offers no risks for patients without pre-assessed contra-indications (e.g. metallic implants). The contrast agent ferumoxtran-10 can cause a contrast reaction during and shortly after administration. Therefore this administration is performed within the hospital under supervision of qualified personnel.

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

o Age > 18 years
o High index of suspicion of locally resectable or borderline resectable pancreatic or periampullary cancer
o The patient must be operable

Exclusion criteria

Pregnancy
Previous pancreatic surgery
Inability to provide informed consent
Contraindications for MRI

Contraindications to USPIO based contrast agents
Prior allergic reaction to contrast media of any type
Contraindications for Butylscopolamine
Contraindications for Glucagon

Study design

Design

Study phase:	3
Study type:	Observational invasive
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-05-2017
Enrollment:	30
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Ferumoxtran-10
Generic name:	Ferumoxtran-10
Registration:	Yes - NL intended use

Ethics review

Approved WMO

Date:	06-10-2015
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Approved WMO

Date:	15-11-2017
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	06-02-2018
Application type:	Amendment
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
EudraCT	EUCTR2015-000822-12-NL
CCMO	NL52657.091.15