Diagnostic accuracy of contrast-enhanced diffusion-weighted MRI for liver metastases of pancreatic cancer: towards adequate staging and follow-up of pancreatic cancer

Published: 30-11-2017
Last updated: 13-04-2024

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Metastases
Study type	Observational invasive

Summary

ID

NL-OMON49213

Source
ToetsingOnline

Brief title
DIA-PANC

Condition

- Metastases

Synonym
Liver metastases

Research involving

Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum
Source(s) of monetary or material Support: KWF

Intervention

Keyword: MRI, Pancreatic cancer, Staging

Outcome measures

Primary outcome

Sensitivity and specificity of CECT and CE-DW-MRI for the detection of liver metastasis.

Secondary outcome

- sensitivity and specificity for CT and MRI to assess local resectability for all patients that underwent surgery

- inter-observer variability for detection of liver metastases

- median and one year survival

- disease free survival

- difference in overall survival in patients with few and many (>5) liver metastases

- effect on patient management of early detection of liver metastases

- cost effective analysis and budget impact analysis

- to evaluate the effect of disease progression and metastatic burden in relation to tumor markers (Ca19.9 and CEA)

Study description

Background summary

Given the dismal prognosis of pancreatic cancer, detecting liver metastases early can avoid inappropriate therapy with associated substantial risks, long-term hospital admissions and high costs, but without survival benefit. The current standard of diagnostic workup with contrast-enhanced CT (CECT) has a poor sensitivity (38-76%) for the detection of liver metastases
As more sophisticated and expensive treatment options emerge, better staging of pancreatic cancer is needed to avoid unnecessary procedures and select the most appropriate treatment strategy. New imaging modalities are available, but their value in staging of pancreatic cancer has not been evaluated yet. Therefore prospective imaging studies are necessary.

Study objective

The main aim of this study is to determine the diagnostic accuracy of contrast-enhanced diffusion-weighted MRI (CE-DW-MRI) in the detection of liver metastases in patients with pancreatic cancer compared to a reference standard of histopathology and follow up imaging.

Study design

Prospective cohort study (inclusion of patients until 138 patients with metastasis are included, with a maximum total of 465 patients). Patients with pancreatic cancer will undergo additional CE-DW-MRI within two weeks from the CECT. CECT and CE-DW-MRI will be read independently by two radiologists. Suspected liver lesions on CECT and/or CE-DW-MRI will be biopsied to obtain histopathology as reference standard. For liver lesions without histopathologic proof of metastases a paired follow-up CECT and CE-DW-MRI serve as a composite reference standard.
Pancreatic resection will be pursued in patients without proven liver or distant metastases. Patients with locally advanced or metastatic disease will be offered palliative treatment. The patients will be asked for informed consent for part 2 of the study, the follow-up, after the baseline scans. Follow-up CECT and CE-DW-MRI will be performed in all patients at 3, 6, and 12 months. When disease progression is taken into account about 400-450 paired follow up scans will be performed. There is also a number of substudies, for which we refer to the research protocol.

Study burden and risks

The extent of burden and associated risks are:

- the extra CT en MRI scans. The first MRI will take place within two weeks after the diagnostic CT. A follow up CT and MRI are scheduled at 3, 6 and 12 months. For these investigations the patient will pay an extra visit to the hospital. The CT and MRI are scheduled on the same day and will take about 15 minutes and 45 minutes respectively.

- radiation dose of the CT:
a) when the patient will undergo his diagnostic imaging in the Radboudumc, an additional perfusion CT will be performed during the routine CT scan. With the CT perfusion scan the enhancement of the tumor can be better evaluated. These extra scans will not prolong the duration of the routine CT scan. There is however an additional radiation dose with an almost negligible risk for this patient category.
b) when the patient will undergo his diagnostic imaging not in the Radboudumc, only the routine CT scan will be performed without the perfusion CT.

- for the MRI there is no burden from radiation dose.

- extra blood samples. Blood samples will be collected on the first day of the visit to the clinic and during follow up at 3, 6 and 12 months: two tubes (3.5ml each) for tumor markers (part of routine diagnostic workup); three tubes (2 times 10ml and 1 time 6ml only at baseline) for the Biobank for future scientific research in the Radboudumc and two tubes (10ml each) for international exosome research (Oslo University Hospital and Champalimaud Centre for the Unknown, Lisbon). The total amount of blood drawn at baseline will 53ml and at each follow up visit (3, 6 and 12 months) will be 47ml.

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

- 18 years and older
- clinical suspicion of pancreatic cancer
- written (signed and dated) informed consent

Exclusion criteria

- Previous treatment for pancreatic cancer (e.g. chemotherapy, radiotherapy, surgery, ablation therapy)
- Concomitant malignancies, except for adequately treated basocellular carcinoma of the skin or in situ carcinoma of the cervix uteri. Subjects with prior malignancies must be disease-free for at least 5 years
- Contra-indications to undergo CT (due to e.g. extreme claustrophobia, untreatable contrast allergy, renal function impairment)
- Contra-indications to undergo MRI (due to e.g. claustrophobia, untreatable contrast allergy, or not MRI compatible medical devices)
- Insufficient command of the Dutch language to be able to understand the patient information or fill in the questionnaires
- Pregnancy

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):	22-12-2017
Enrollment:	465
Type:	Actual

Medical products/devices used

Generic name:	MRI (Magnetic Resonance Imaging)
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	30-11-2017
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	07-03-2018
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	26-11-2018
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	14-08-2019
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
CCMO	NL60473.091.17