MR-guided biopsy of liver metastases in patients with suspected pancreatic cancer

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To obtain histopathology from liver lesions, visible on MRI but which cannot be biopsied with transabdominal ultrasound, using MR-guided biopsy.

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

Summary

ID

NL-OMON47537

Source
ToetsingOnline

Brief title
META-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: Ministerie van OC&W

Intervention

Keyword: Liver biopsy, Metastases, MRI, Pancreatic cancer

Outcome measures

Primary outcome

Feasibility of MR-guided liver biopsy

Secondary outcome

- Percentage representative histopathology of liver lesions.

- Procedure duration

- Procedure workflow

- Occurrence of procedure related complications/adverse events

- Lesion size

- Skin-to-target length

- Histopathologic analysis of metastases. Correlation between different aspects

of lesions on MRI and HE-staining. Amount of fibrosis, tumor grade,

angiogenesis (MVD).

- Optimization of imaging protocol during liver biopsy procedure

Study description

Background summary

CECT, mostly used in the diagnostic workup of pancreatic cancer, is probably insufficient for detecting liver metastases, especially subcentimeter lesions. With CE-DW-MRI we can possibly improve detection of liver metastases, improving staging of pancreatic cancer. As most of these lesions are not visible on transabdominal ultrasound, it is not possible to obtain a histopathologic biopsy in all patients in order to prove the presence of liver metastases. Demonstration of liver metastases is of the utmost importance because their presence precludes a curative resection of the pancreatic tumor and will change

the treatment plan towards palliative chemotherapy. Therefore we want to perform a MR-guided biopsy, as the next minimal invasive step, to obtain histopathologic proof of liver metastases.

Study objective

To obtain histopathology from liver lesions, visible on MRI but which cannot be biopsied with transabdominal ultrasound, using MR-guided biopsy.

Study design

A pilot feasibility study with 20 patients with suspected pancreatic cancer and suspect liver lesions on CE-DW-MRI. Patients in which the suspect liver lesions cannot be biopsied with transabdominal ultrasound a MR-guided biopsy will be performed. This procedure will be performed in the Medical Innovation & Technology expert Center (MITec), a state-of-the-art centre in the surgical complex with an MRI-suite where MR-guided interventions can be performed in an controlled environment next to 2 operating rooms. In the MITeC a MRI of the liver is performed to localize the liver lesion(s). After local anaesthesia a liver lesion is biopsied. During the biopsy procedure new MR images are acquired to guide the needle exactly towards the liver lesion. Preferably two lesions will be biopsied. After the procedure the intraprocedural MR images will be evaluated by an independent radiologist, he will determine if the biopsy location is representative of the lesion location. This radiologist will be blinded for the outcome of the histopathology. The biopsy specimens are routinely histopathologically analyzed for the presence of metastasis.

The first 5 patients will be used to determine the technical feasibility of the technique. The 15 following patients will be used to validate and analyze the method.

Study burden and risks

Patients eligible for this study have suspicious liver lesions on MRI which cannot be biopsied with ultrasound guided biopsy. By participating in this study we attempt to obtain representative histopathology through MR-guided biopsy. Hereby patients might benefit from participation because detection of liver metastases precludes an unnecessary pancreas resection with its associated morbidity and mortality. This will prevent surgery related loss of quality of life in the limited life expectancy of patients with metastatic disease. Furthermore, chemotherapy can start timely, without delay because of recovery from surgery. Patients will undergo a MRI scan of the liver in the MITeC to guide the liver biopsy procedure, which will be performed under local anaesthesia. Preferably two liver lesions will be biopsied. The risks of MR-guided biopsy are comparable to a routine ultrasound guided biopsy. It is justified to conduct the study in this patient group, because it cannot be

conducted without the participation of subjects with pancreatic cancer and suspicious liver lesions on MRI.

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

- Age older than 18 years.
- Patients with on CECT suspected pancreatic cancer and liver lesions detected by CE-DW-MRI.
- Liver lesions cannot be biopsied with transabdominal ultrasound.
- Written (signed and dated) informed consent.

Exclusion criteria

- Successful ultrasound-guided liver biopsy with proven metastases.
- Insufficient command of the Dutch language to be able to understand the patient information
- Pregnancy
- Contraindication for MRI

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	03-04-2019
Enrollment:	20
Type:	Actual

Medical products/devices used

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

Ethics review

Approved WMO

Date:	27-08-2018
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	NL61918.091.18