Pilot study: The use of PET-MRI in the follow-up of RFA treated colorectal liver metastases

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

Summary

ID

NL-OMON38868

Source
ToetsingOnline

Brief title
PET-MRI after RFA

Condition

- Hepatobiliary neoplasms malignant and unspecified
- Metastases
- Hepatobiliary therapeutic procedures

Synonym
Local site recurrence after radiofrequency ablation of colorectal liver metastases; synonyme: treatment failure of radiofrequency ablation of metastases in the liver derived from colorectal carcinoma

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Catheter Ablation, FDG-PET, Liver Neoplasms/secondary, MRI

Outcome measures

Primary outcome

Primary outcome is the ability of PET-MRI in the detection of LSR in the liver compared to ceCT of the liver and PET-CT referred to histological findings or clinical follow-up.

Secondary outcome

Secondary outcomes are the inter-observer variability, the ability to diagnose new intrahepatic lesions and in what way PET-MRI is able to influence future treatment compared to PET-CT and ceCT. The patients satisfaction concerning the PET-MRI will be examined with a questionnaire.

Study description

Background summary

The main area of concern regarding radiofrequency ablation (RFA) or microwave ablation (MWA) of colorectal liver metastases (CRLM) is the risk of developing a local site recurrence (LSR). Imaging plays a key role in diagnosing LSR after RFA or MWA liver treatment. When LSR is diagnosed adequately and timely, optimal effect of repeated (minimal invasive) local treatment may be obtained. So far a contrast enhanced (ce) CT scan is generally used for follow-up, However, post-treatment effects in the ablation margin may complicate an adequate diagnosis of LSR for which the addition of FDG-PET helps to differentiate between metabolic active tumor tissue and inactive post-ablation mass. Therefore an integrated FDG PET-CT is favourable over CT alone and the combination of both is standard of care in our centre. Liver MRI with contrast

outperforms CT in the detection of small hepatic metastases (<1 cm), but its role is not yet established for the follow-up after RFA or MWA. Therefore, the combination of FDG PET to determine metabolic activity with the ability of the MRI to detect small lesions may add to timely and correctly diagnosing a LSR. This may lead to earlier initiation of effective treatment. With the recent launch of PET-MRI, these two advantages can be combined.

Study objective

The primary objective of this study is to evaluate the ability of PET-MRI to detect LSR during the first year of follow-up after RFA treatment of CRLM as compared with ceCT and PET-CT. Standard reference will be histology (when available) or clinical follow-up.

Study design

Multi centre pilot study

Study burden and risks

All participating patients will receive follow-up according to normal standards in our hospital (ceCT of the liver and a PET-CT 3-4 monthly in the first year). These imaging modalities are currently leading in the evaluation of local response to RFA and MWA treatment and to diagnose new intra- and extrahepatic metastatic disease. Therefore in this study, the decision on treatment will not be made based on the results of the PET-MRI, but based on PET-CT and ceCT, sometimes in combination with CEA at the surgeons or oncologists discretion. The PET-MRI images will be evaluated separately and results will be compared to PET-CT and ceCT. The additional risks for participating patients with normal renal function, when normal in- and exclusion criteria for MRI research are being followed are limited. There is no increased exposure to radiation and the patients only need a single dose of FDG for both PET-CT and PET-MRI. The risk on nefrogenic systemic fibrosis after use of gadolinium is negligible in patients with adequate renal function. Undergoing a PET-MRI of the liver will cost the participant extra time; 45 minutes extra for scanning protocol. We will put much effort in reducing the waiting time in between scans as much as possible. Travel time may be longer for than usual for patients from the Gelderse Vallei.

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

Histological or cytological documentation of primary colorectal tumor
Radiological or histological prove of one or more CRLM or radiological prove of a LSR after previous RFA/MWA treatment for CRLM
CRLM or LSR treated with RFA/MWA or RFA/MWA in combination with resection
Follow-up imaging performed in VUmc medical centre
Age ³ 18 years
Life expectancy of at least 1 year
eGFR > 60 or hydration according to protocol before scanning

Exclusion criteria

Cirrosis or steatosis
Chemotherapy * 6 weeks before scanning (during the entire study)
Pregnant or breast-feeding subjects
Allergy to contrast media
Patients developing recurrent intrahepatic disease that require resection of the ablated lesion
eGFR < 60, unless hydration according to protocol is possible

General exclusion criteria to undergo MRI

Study design

Design

Study phase:	2
Study type:	Observational non invasive
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-07-2013
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO Date:	07-06-2013
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	11-09-2013
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
ClinicalTrials.gov	NCT01895673
CCMO	NL43058.029.13