Use of the PET/CT [18F]-Fluorocholine: Diagnostics and Follow-up of Hepatocellular Carcinoma

Published: 03-03-2011
Last updated: 06-05-2024

For further details see - Protocol section: 2 - Aimo Assessment of the accuracy of the FCH PET/CT scan in diagnosing HCC. o Assesment of radical surgical resection, using the FCH PET/CTscan.o Assesment of recurrence after surgical resection, using...

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

Summary

ID

NL-OMON36749

Source
ToetsingOnline

Brief title
FCH PET/CT and HCC

Condition

- Hepatobiliary neoplasms malignant and unspecified
- Hepatobiliary therapeutic procedures

Synonym
hepatocellular carcinoma, livercancer

Research involving
Human

Sponsors and support

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

Intervention

Keyword: fluorocholine, Hepatocellular carcinoma, liver, PET/CT

Outcome measures

Primary outcome

For further details see - Protocol section: 2 -

1. Sensitivity and specificity of the FCH PET/CT scan

(in reference to current golden standard of:)

- Histological outcome (and differentiation of the tumor)

OR:

- Outcome of imaging results corresponding with HCC

Secondary outcome

For further details see - Protocol section: 2 -

1. Diagnosis of HCC, spread of the disease or metastatic disease in an earlier

stage, compared to diagnosis with conventional imaging modalities.

2. Change in treatment

3. Differentiation grade of the HCC based on the SUV-ratio (golden standard is

histological outcome)

Study description

Background summary

For further details see - Protocol section: 1 -

With this study we want to ease the challenge of non-invasive diagnosis and follow-up of hepatocellular carcinomas: We hope to correctly, and in an early stage, assess the diagnosis, recurrence and disease progression of HCC to ultimately optimize patient*s treatment and follow-up.

The AASLD has established a set of criteria for diagnosing HCC. The current guidelines recommend radiological imaging (MRI and CT). When 2 imaging modalitities show a hypervascular lesion in arterial phase, with signs of (rapid) wash-out, an HCC is most likely. Small HCC (< 20mm) are difficult to diagnose with non-invasive techniques alone, especially in the cirrhotic liver. When diagnosis remains uncertain, histological affirmation is recommended. During follow-up of HCC imaging results are complicated by the often intervening effects of treatment, including necrosis, local inflammation and fibrosis.The disappointing sensitivity of the imaging modalities calls for an accurate non-invasive diagnostic tool.

[F18] fluorocholine (FCH) PET/CT
With the use of Positron Emission Tomography (PET) the metabolism of a specific compound within an organ or tumor can be assessed, when labeled with a radioactive tracer. The diagnostic accuracy of the conventional glucose PET/CT scan (FDG PET) however, is disappointing, especially in well differentiated HCC. In *a proof of concept* study by Talbot et al, the FDG PET/CT showed a sensitivity of only 56%, compared to a 100% sensitivity of the FCH PET in lesions larger then 9mm. They concluded that FCH is potentially useful in the initial detection of HCC or in the detection of recurrent disease. Furthermore, study suggests that differentiation between vital and non-vital tumor tissue can be made using the FCH tracer. Altogether, the PET/CT FCH is a promising diagnostic additive and possibly employable in the follow-up of HCC after resection, local ablation, TACE and drug treatment to assess treatment effectiveness, recurrence and metastatic disease.

Hypothesis
Accurate assessment of diagnosis, recurrence, disease progression or metastases of hepatocellular carcinoma is possible using the 18F-fluorocholine PET/CTscan.

Study objective

For further details see - Protocol section: 2 -

Aim
o Assessment of the accuracy of the FCH PET/CT scan in diagnosing HCC.

o Assesment of radical surgical resection, using the FCH PET/CTscan.
o Assesment of recurrence after surgical resection, using the FCH PET/CTscan.

o Assesment of treatment response (to RFA, TACE and Sorafenib) in palliative patient care, using the FCH PET/CTscan.

o Predicting grade of differentiation of HCC (strongly correlated with prognosis) using the FCH PET/CT

Study design

Observational prospective clinical trial

Study burden and risks

PET/CT:
The FCH PET/CT scan will be combined with the multiphase CTscan that is standard patient care for HCC.
The radiopharmacon is administered via the same route as the contrast agent of the CTscan, and no allergies are known against this agent. The scan will take an extra hour and will be performed three times over a period of approximately 9-12 months.

Bloodsamples:
Before every FCH PET/CT a bloodsample will be taken as is part of standard patient care. (serum creatin and alpha fetoprotein)
During every FCH PET/CT a venous bloodsample is taken at 5, 10, and 15 minuts post 18F-FCH injection, drawn from the intravenous line over which the 18F-FCH was injected. No additional venous punction is necessary. The first 5 mL of the first sample (t=5) will be disregarded and destroyed, 4mL will be used for assessment of serum CRP levels by the LAKC, and 2mL will be used for assessment of radioactivity. Additional assessment of radioactivity in the venous blood will take place at t=10 and t=15 post 18F-FCH injection in 2mL whole blood. Adding up to a total of 15mL blood per patient per scan.

Benefit:
Recurrence, metastases or progression of HCC could be recognized sooner, thus making early adiquate therapy possible for the patients participating in the trial or for patients with HCC in general.

Contacts

Public
Academisch Medisch Centrum

Meibergdreef 9
1105 AZ Amsterdam
NL
Scientific
Academisch Medisch Centrum

Meibergdreef 9
1105 AZ Amsterdam
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1. 18 years of age or older
2. Signed informed consent
3. Affirmed or suspected diagnosis of HCC based on current standard of care and guidelines
4. Expected (partial) treatment and follow-up at the AMC

Exclusion criteria

Exclusioncriteria in regard to the multiphase CT scan combined with the PETscan include:
1.1. Renal impairment and allergy to the contrast agent. These patients undergo pre-treatment according to the AMC radiology protocol, after which the combined FCH PET / (multiphase) CT scan will be performed.

1.2. If patients cannot undergo the multiphase CT scan, an MRI is performed instead and FCH PET/CT is made with a low dose CT scan and no contrast is used.
1.3. If however no imaging studies with CT or MR are possible, because of contraindications against both imaging modalities, patient is excluded.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-11-2010
Enrollment:	100
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
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	NL32753.018.10