Extended PET scanning in patients with incurable hepatocellular carcinoma (HCC) treated with sorafenib.

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Primary objective: - to test the hypothesis that an initial negative PET scan can be change in 4 months in a positive PET scan.Secondary objective:- to test the hypothesis that a negative PET scan is related to a less aggressive tumor with an...

Ethical review	Approved WMO
Status	Will not start
Health condition type	Hepatobiliary neoplasms malignant and unspecified
Study type	Observational non invasive

Summary

ID

NL-OMON32355

Source
ToetsingOnline

Brief title
Extended PET scanning in incurable hepatocellular carcinoma

Condition

- Hepatobiliary neoplasms malignant and unspecified

Synonym
hepatocellular carcinoma, liver cancer

Research involving
Human

Sponsors and support

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

Intervention

Keyword: hepatocelullar carcinoma, PET scan

Outcome measures

Primary outcome

An initial negative PET will change in a positive scan

Secondary outcome

Relation initial PET negative scan and survival benefit

Study description

Background summary

Hepatocellular carcinoma (HCC) is a primary tumor of the liver, which usually develops in the setting of chronic liver disease, particularly viral hepatitis.
The diagnosis of HCC can be difficult, and often requires the use of serum markers, one or more imaging modalities, and histologic confirmation. Ideally, tumors should be detected when they are small in patients who are able to withstand therapy. However, HCC is frequently diagnosed late in its course because of the absence of pathognomonic symptoms and the liver's large functional reserve. As a result, many patients have untreatable disease when first diagnosed. The median survival following diagnosis is approximately 6 to 20 months. Large tumor size, vascular invasion, poor functional status, and nodal metastases are all associated with a poor outcome.
A member of the group of protein tyrosine kinases, Sorafenib, has recently been found to improve survival in modest terms, however as this is sofar the only systemic approach with activity, this finding has generated much interest.The manufacturer of the drug (Bayer) has activated a compassionate need program for Sorafenib, in addition to its registered indication for renal cell cancer. The nature of this group of drugs is that response evaluation is cumbersome in the classical way using the serum tumor marker AFP, CT or other dimensional orientated techniques. The tumor marker AFP can often not be used as an surrogate marker of response as not all tumors have an increased marker and on the otherhand many other factors as hepatitis C activity can influence the AFP level. The dimensional oriental techniques do have problems as usually responses involve central necrosis that do not involve the outside borders for some period of time. In addition HCC often has no outside borders but grows infiltrating in the normal liver parenchyma. Because of these consideration evaluation of response to tyrosinase inhibitors is best done using PET

scanning, as is the case in Gastro intestinal stroma tumors and kidney cancer. In contrast with these tumors, liver cell cancer is PET positive in only appr. 60% of cases, this may related to the more aggressive feature of the tumor. In these patients a diagnosis of response has to rely on scanning with the addition of markers. Often clinical parameters will have to be used. The subject of this study is the question if this group of patients has a survival that is different from those with a positive scan, because of inherent differences in tumor biology. On the other hand a negative PET scan could be merely a stage of the tumor in time. In addition to registration of clinical data in the follow up we will test the hypothesis that a stage difference is involved by proposing a second PET scan in initially PET negative patients 4 months after start of treatment

Study objective

Primary objective:
- to test the hypothesis that an initial negative PET scan can be change in 4 months in a positive PET scan.

Secondary objective:
- to test the hypothesis that a negative PET scan is related to a less aggressive tumor with an increased median overall survival.

Study design

Type: observationeel onderzoek

Design: pilot study

Study burden and risks

The burden or risk associated with this study is considered to be low, there is no benefit for the patient

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

1. Incurable HCC,
2. Treatment with sorafenib is/will be started
3. At least 18 years of age
4. A life expectancy of at least 3 month
5. Signed written informed consent
6. Able to comply with the protocol
7. Tumor response confirmed by CT-scan after 3 month (t=0 is start the sorafenib)

Exclusion criteria

1. Dementia or altered mental status that would prohibit giving of informed consent
2. Pregnant or lactating women.

Study design

Design

Study type: Observational non invasive
Masking: Open (masking not used)

Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Will not start
Start date (anticipated):	01-12-2007
Enrollment:	10
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL20149.042.07