Contrast Enhanced Ultrasound and Urine Mass Spectometry in Patients with Hepatocellular Adenoma

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The purpose of this study is to improve the diagnosis and management of hepatocellular adenoma.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Hepatic and hepatobiliary disorders
Study type	Observational invasive

Summary

ID

NL-OMON36784

Source
ToetsingOnline

Brief title
nvt

Condition

- Hepatic and hepatobiliary disorders
- Hepatic and biliary neoplasms benign

Synonym
Liver adenoma

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Contrast enhanced ultrasound, Hepatocellular adenoma, Urine mass spectometry

Outcome measures

Primary outcome

What is the sensitivity of CEUS with SonoVue compared to diagnostic modalities

conducted in the past (radiology, histology)?

Secondary outcome

What is the behavior of hepatocellular adenoma during and after menopause?

Is it possible to classify hepatocellular adenoma, according to the subgroups

of the Bordeaux group, based on contrast ultrasonography?

Are there specific biomarkers (natural peptides and metabolites) in urine that

can demonstrate hepatocellular adenoma?

What is the quality of life of patients with hepatocellular adenoma?

1. with certainty of hepatocellular adenoma (> 6 months ago)

2. who are in a diagnostic process for hepatocellular adenoma

Study description

Background summary

Contrast ultrasonagraphy is an easy and inexpensive imaging modality without side effects. Using contrast ultrasonography, we believe we can make a clear distinction between hepatocellular adenoma and focal nodular hyperplasia (a benign tumour of the liver that generally does not require treatment and follow-up, in contrast to hepatocellular adenoma). In the near future contrast ultrasonography could be beneficial and could shorten the waiting time for treatment. An easy and good method for identifying hepatocellular adenoma may lead to a faster treatment. The purpose of this study is to improve the diagnosis and management of hepatocellular adenoma.

Besides new imaging techniques, there are new technologies that improve the diagnosis of adenomas in the field of expertise of biomarker. Human biological fluids contain various types of biomarkers that can be specific and sensitive for many diseases. Urine is a human sample that can be easily obtained. Using mass spectrometry of urine, we hope to find specific biomarkers that can demonstrate hepatocellular adenoma.

Study objective

The purpose of this study is to improve the diagnosis and management of hepatocellular adenoma.

Study design

Patients aged 18 years and older, previously discharged from follow-up of the Erasmus MC with the diagnosis or probable diagnosis of hapatocellular adenoma, are eligible for the study. In the past, these patients were seen at the surgery outpatient clinic and / or hepatogastroenterology outpatient clinic of the Erasmus MC. After consent of the treating physician, patients will be asked to participate in this study.

Patients will be informed after an official reflection period of 1 week. Blood and urine samples of all patients will be collected. Besides that, all patients will undergo contrast ultrasonography and patients will be asked to complete a questionnaire.

Study burden and risks

Contrast ultrasonography takes about 20 minutes. Complications of the contrast agents used in contrast ultrasonography contain allergic reactions in rare cases. Serious adverse events of contrast ultrasonography may occur in <0.0002% of cases. Venipuncture (venflon) will be conducted once. Collection of urine is carried out by the patient. Patients will experience minimal impact of this study, without additional risks.

Contacts

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Scientific

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Persons 18 years and older, discharged from follow-up of the Erasmus MC with the diagnosis or probable diagnosis of hepatocellular adenoma. Informed consent must be signed.

Exclusion criteria

Persons under 18 years.

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):	15-05-2012
Enrollment:	78
Type:	Actual

Ethics review

Approved WMO

Date:	20-07-2011
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL34105.078.10