Assessment of Choline levels in focal nodular hyperplasia (FNH), hepatocellular adenoma (HCA), and hepatocellular carcinoma (HCC) using proton Magnetic Resonance Spectroscopy.

Published: 03-03-2011
Last updated: 04-05-2024

To determine the choline levels of FNH, HCA and HCC using proton Magnetic Resonance Spectroscopy (expressed as parts per million).

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

Summary

ID

NL-OMON36577

Source
ToetsingOnline

Brief title
Choline levels in livertumors.

Condition

- Hepatobiliary neoplasms malignant and unspecified
- Hepatic and biliary neoplasms benign

Synonym
focal nodular hyperplasia, hepatocellular adenoma (livercel tumor), 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: Choline, Liver tumor, Magnetic Resonance Spectroscopy

Outcome measures

Primary outcome

1. Choline levels: Expressed as parts per million.

The number of parts per million is calculated by dividing the difference in

frequency (in hertz) of choline and water, by the operating frequency of the MR

imaging system (in hertz).

2. Histological outcome (obtained from patient's medical records)

3 Outcome of imaging modalities used to assess diagnosis (multiphase CT and

MR), only if histology is not obtained and imaging results are characteristic

and definite in the diagnosis of FNH, HCA or HCC.

Secondary outcome

not applicable

Study description

Background summary

Hepatocellular adenoma (HCA) and focal nodular hyperplasia (FNH) are benign liver tumors. Hepatocellular carcinoma (HCC) is a malignant tumor of the liver. The PET/CT scan with a choline radiopharmacon is used in the diagnostic work-up of these liver lesions. Choline is an essential nutrient and is used in

the human body for the synthesis of phosphatidylcholine and sphingomyelin, two phospholipids which are structural components of all human cell membranes. According to recent study conducted at our center, the PET/CT scan with the choline tracer shows no uptake in HCA, but surprisingly it does in FNH. Malignant tumor cells are known to have rapid cell duplication and therefore have a higher uptake of choline as a substrate for cell membranes. HCCs for example show high uptake of the choline tracer and elevated choline levels on Proton Magnetic Resonance Spectroscopy (MRS). With this imaging technique accurate assessment of tissue compounts like choline can be non invasively acquiered.

Study objective

To determine the choline levels of FNH, HCA and HCC using proton Magnetic Resonance Spectroscopy (expressed as parts per million).

Study design

- Prospective observational diagnostic single center clinical study.
- The MRS will be evaluated by a radiologist blinded for patient history, previous imaging results and histological outcome.

Study burden and risks

The proton MR Spectroscopy (1H-MRS) is an additional imaging modality performed once and will take approximately 30-40 minutes. The MRS is a non-invasive, non-ionizing examination, during which the participant will have to lie still on his/her back in a MRI scanner. No contrast medium will be administered. Participating in the study will require one extra visit to the hospital. Participation has no direct advantage for the participant. Incidental findings on the MRI scan will be reported to both the participant and their consulting gastroenterologist or general practitioner. Patients are not delayed in treatment for their disease. There will be little extra physical and psychological discomfort associated with participation.

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. Affirmed diagnosis of FNH, HCA or HCC based on:
- Histopathological proof
- If no histological proof was obtained: results of imaging modalities characteristic for FNH, HCA or HCC. These characteristics of MR and CT imaging include:
* HCA: Hypervascular lesion in the arterial phase and signs of bleeding and/or fat within the lesion.
* FNH: Hypervascular lesion in the arterial phase, and the presence of a central scar.
* HCC: Hypervascular lesion in the arterial phase, followed by wash-out during the portal or late phase AND positive patient history for risk factors in HCC development including hepatitis B and C, haemochromatosis, alcohol abuses and cirrhosis OR elevated alpha fetoprotein 1.
2. Size of the lesion: > 2 cm.
3. 18 years of age or older.
4. Before patient registration, written informed consent must be given according to ICH/GCP, and national/local regulations.

Exclusion criteria

1. Contraindications for MR imaging:
- Pacemaker, medicine pump, neurostimulator, claustrophobia, iron slivers in the eye, brace.
- Irremovable body piercing, iron particles in the body.

- Patients with extreme obesity (will not fit in the bore of the MRI)

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	15
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	NL35184.018.10