Addition of GAAD score to imaging surveillance for early identification of liver cancer.

Published: 05-03-2024
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To study the impact of addition of the GAAD score to imaging in patients with chronic liver disease eligible for HCC surveillance.

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

Summary

ID

NL-OMON56668

Source
ToetsingOnline

Brief title
ADRENALIN

Condition

- Hepatobiliary neoplasms malignant and unspecified

Synonym
Hepatocellular carcinoma, liver cancer.

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Stichting voor Lever en Maag-Darm Onderzoek

Intervention

Keyword: Chronic hepatitis B, GAAD score, Hepatocellular carcinoma

Outcome measures

Primary outcome

Diagnostic accuracy of the GAAD score (cut-off 2.57) for detection of HCC

(overall and by BCLC stage), expressed using sensitivity, specificity, negative

predictive value and positive predictive value.

Secondary outcome

nvt

Study description

Background summary

Hepatocellullar carcinoma (HCC) is a major cause of death among patients with chronic liver disease. Current guidelines therefore recommend 6 monthly HCC surveillance using liver imaging in all patients with cirrhosis, and in a subset of non-cirrhotic patients with chronic hepatitis B, chronic hepatitis C or NASH (1). Since the sensitivity of liver imaging is limited, guidelines suggest addition of biomarkers to imaging to increase the probability of detecting early-stage HCC. Recent studies indicate that a risk score comprising patient gender, age, and AFP with AFP-L3 and des-carboxy-prothrombin (the GALAD score) has superior diagnostic accuracy, and could help improve HCC detection (2). A simplified version of GALAD, the GAAD score, was recently shown to yield comparable results, and has subsequently been implemented in liver clinics (3).

References:
1. European Association for the Study of the Liver. Electronic address eee, European Association for the Study of the L. EASL Clinical Practice Guidelines: Management of hepatocellular carcinoma. J Hepatol. 2018;69(1):182-236.
2. Yang JD, Addissie BD, Mara KC, Harmsen WS, Dai J, Zhang N, et al. GALAD Score for Hepatocellular Carcinoma Detection in Comparison with Liver Ultrasound and Proposal of GALADUS Score. Cancer Epidemiol Biomarkers Prev. 2019;28(3):531-8.
3. Lik-Yuen Chan H, Berg T, De Toni EN, Kudo M, Trojan J et al. A comparative analysis of Elecsys GALAD and Elecsys GAAD score to detect early-stage

hepatocellular carcinoma in an international cohort. 2022.

Study objective

To study the impact of addition of the GAAD score to imaging in patients with chronic liver disease eligible for HCC surveillance.

Study design

Prospective cohort study.

Study burden and risks

The GAAD score is already available in the clinic and assessed in patients eligible for HCC surveillance regardless of participation in this study. Participation in this follow-up study is not associated with additional risks to the patient.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

- All patients with cirrhosis
- Non-cirrhotic chronic hepatitis B patients meeting any of the following criteria: positive family history for hepatocellular carcinoma, intermediate-high aMAP and/or (m)PAGE-B score (if non-Caucasian)
- Non-cirrhotic chronic hepatitis C patients (with or without SVR) with a history of F3 fibrosis (based on histology or liver stiffness assessment)
- Non-cirrhotic NASH patients with a history of F3 fibrosis (based on histology or liver stiffness assessment)

Exclusion criteria

- Diagnosis with any other cancer other than non-melanoma skin cancer
- History of hepatocellular carcinoma
- Women who are pregnant or lactating
- Patient with glomerular filtration rate <45 ml /min/1.73 m2
- Unwillingness or inability to undergo both CT and MRI imaging
- Life expectancy <2 years
- Use of vitamin K antagonists

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting

Start date (anticipated):	08-03-2024
Enrollment:	1000
Type:	Actual

Medical products/devices used

Generic name:	Elecsys GAAD - cobas
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	05-03-2024
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	10-07-2024
Application type:	Amendment
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	NL85202.078.24