Validation of a Short MRI Surveillance (SMS) protocol for hepatocellular carcinoma screening in practice.

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To evaluate our proposed SMS protocol in high-risk patients and compare it to a bi-annual US screening.

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

Summary

ID

NL-OMON53951

Source
ToetsingOnline

Brief title
Validation of SMS protocol for HCC screening in High-risk patients

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: KWF Dutch Cancer Society Delflandlaan 17 1062 EA;Amsterdam

Intervention

Keyword: HCC screening, Hepatocellular Carcinoma, Short MRI Surveillance (SMS)

Outcome measures

Primary outcome

The primary study objective of this study is to compare the sensitivity of the SMS protocol with that of US surveillance for the detection of HCC. The reference standard to which both strategies will be compared is the full-liver MRI.

Using standard methodology for diagnostic research we will calculate the sensitivity (2x2 contigency tables). Additionally, the specificity, positive predictive value (PPV) and negative predictive value (NPV) of the SMS protocol and US will be calculated. McNemar*s test will be used to test whether the potential difference in sensitivity between SMS and US is statistically significant.

Secondary outcome

The cost-effectiveness analysis will be performed from a healthcare perspective using costs per detected cancer as outcome. Hereto, we measure all direct medical costs which will be collected from hospital databases and literature using the year 2023 as price level
within both diagnostic pathways. The cost-effectiveness analysis will be perfomed according to the Dutch guidelines and by using a Markov model.

The final outcome will be an incremental cost-effectiveness ratio (ICER). This

ratio expresses the difference in costs
between SMS and US pathway per unit of health gain (detected cancer and quality adjusted
life years (QALYs)). The uncertainty around the estimates will be addressed using
deterministic and probabilistic sensitivity analyses.

We need information on the QALYs and ICER gained by diagnosis of HCC with MRI versus US. It is safe to assume that the prognosis of HCC detected at an early stage with SMS is more favourable than the prognosis of HCC detected in a more advanced stage by US.
Data from this trial, literature and expert opinion will be used to calculate the impact of earlier detection of smaller lesions on outcomes (i.e. progression free survival and overall survival). In combination with the fact that the early HCC require less extensive treatment,
we expect that valuable QALYs and ICER might be gained by using SMS.

We hypothesize that screening with biannual SMS is more cost-effective than screening with biannual US, with improved clinical outcomes at a reasonable cost. If the hypothesis is proven correct, then further research may show whether annual screening with SMS will
suffice instead of semi-annual SMS, based on the rational that our retrospective study as described above was performed with data derived from patients with annual screening with full liver MRI. This may eventually prove

that the direct costs of annual SMS roughly equals

that of bi-annual US, but at an improved cost-effectiveness considering

lifetime costs, QALY and ICER

Study description

Background summary

Hepatocellular Carcinoma (HCC) comprises 75-85% of all liver cancer cases. The current guidelines recommend bi-annual surveillance using ultrasound (US) for high-risk patients.
US is widely available, however, US has a low sensitivity for detection of early stage (small) HCC lesions. It is therefore of importance that new surveillance modalities are developed. In this study, a Short MRI Surveillance (SMS) protocol will be evaluated and will be compared to US.

Study objective

To evaluate our proposed SMS protocol in high-risk patients and compare it to a bi-annual US screening.

Study design

This study is a prospective, multicentre, patient cohort study. Patients will be recruited from six participating medical centers in The Netherlands, including a total of 470 patients.

Study burden and risks

We have estimated an average of 2.5 paired (US and SMS) screenings for patients, taking into account the dynamic study cohort during three years. The US and SMS will be scheduled on the same day to limit inconvenience for patients. In case of suspicious lesions on US and/or SMS patients will be invited for a clinical applied full liver diagnostic MRI (Full MRI) within 2 weeks.

Before the end of the study period an online questionnaire will be conducted for included patients with their permission. This questionnaire will be performed, in cooperation with the NLV, to evaluate patient experience and confidence with the SMS protocol.

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. Patients age >= 18 years at time of enrolment
2. Patients diagnosed with chronic hepatitis B
a. All patients diagnosed with chronic hepatitis B and liver cirrhosis
b. The following patients diagnosed with chronic hepatitis B without liver cirrhosis
i. East-Asian men >= 40 years of age
ii. East-Asian women >= 50 years of age
iii. Patients from sub-Saharan Africa >= 20 years of age
iv. Patients with HCC family history
3. Patients diagnosed with non-hepatitis B cirrhosis
a. Patients diagnosed with hepatitis C
b. Patients diagnosed with alcoholic cirrhosis

c. Patients diagnosed with hemochromatosis
d. Patients diagnosed with primary biliary cirrhosis

Exclusion criteria

1. Patients aged <= 18 years at time of enrolment
2. Patients who decline to sign the written informed consent form
3. Patients with general contra-indications for undergoing MRI examination

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):	01-04-2023
Enrollment:	470
Type:	Anticipated

Medical products/devices used

Generic name:	magnetic resonance scanners for the whole body; Signa Artist 1.5T;Versie Rev
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	16-05-2023
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	NL82538.078.23