Optimization of spleen VCTE examinations with FibroScan

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Main objective : To develop a spleen examination dedicated to overweight or obese patients and assessits applicability.Secondary objectives :1. Develop a spleen exam dedicated to patients usually measured with the S+ probe and assess its...

Ethical review	Approved WMO
Status	Completed
Health condition type	Hepatic and hepatobiliary disorders
Study type	Observational non invasive

Summary

ID

NL-OMON53533

Source
ToetsingOnline

Brief title
M139

Condition

- Hepatic and hepatobiliary disorders

Synonym
Liver disease - Portal Hypertension

Research involving
Human

Sponsors and support

Primary sponsor: Echosens
Source(s) of monetary or material Support: Echosens

Intervention

Keyword: FibroScan, Optimization, Spleen Stiffness Measurement, VCTE

Outcome measures

Primary outcome

Success rate of the spleen stiffness measurement (SSM) exam with the XL probe, defined with at least 8 valid measurements after the post-processing phase.

Secondary outcome

1. Success rate of the SSM exam with the S probe, defined with at least 8 valid measurements after the post-processing phase.

2. Success rate of the SSM exam with the optimized M probe, defined with at least 8 valid measurements after the post-processing phase.

3. Improvement of the applicability with the STT and the automatic depth adaptation mode enabled.

Study description

Background summary

Chronic Liver Diseases (CLDs) are usually asymptomatic, progressive, and ultimately potentially fatal diseases. Cirrhosis is the end stage of all CLDs and the principal complication is the portal hypertension (PH) which is the result of congestion within the liver that causes an impaired blood flow from the portal vein to the hepatic vein. The gold standard for diagnosing PH is by measuring the Hepatic Venus Pressure Gradient (HVPG), PH is defined as a HVPG > 6 mm Hg and it will be considered as clinically significant (CSPH) when it is HVPG > 10 mm Hg. The HVPG values correlate with the risk of esophageal varices (EV) development and clinical decompensation when >= 10 mmHg, and with the risk of variceal bleeding when >= 12 mmHg. However, this method is invasive, costly and it is only available in specialized centers.

PH may have different consequences such as hepatocellular carcinoma (HCC), ascites, esophageal/gastric varices, and hepatic encephalopathy.

The development of EV in cirrhotic patients, as well as their potential bleeding, represent one of the most severe and life-threatening complications of cirrhosis. The prevalence of EV among cirrhotic patients is about 50-60%, with an incidence of variceal bleeding of approximatively 5% to 15% yearly, and a variceal re-bleeding rate of 30% to 40% within the first 6 weeks. Furthermore, gastro intestinal variceal bleeding is associated with significant mortality up to 30% in adults and between 0-15% in children. Upper gastrointestinal endoscopy (EGD) is the reference diagnostic tool for detecting the presence of EV, for estimating their grade and for the recognition of indicators of high-bleeding risk EV (HRV) but this method, as for HVPG, is invasive and costly.

Therefore, several non-invasive methods (serum biomarkers and elastography techniques) have been proposed to predict the degree of PH and the presence of EV.
In this context, in 2019, Echosens has developed a new FibroScan device intended to provide Spleen Stiffness Measurement (SSM)8 . A European multicenter study was conducted with 260 patients included (Stefanescu et al, 2019). It has shown an excellent applicability rate of the SSM@100 Hz (88%) and a diagnostic accuracy of SSM@100Hz for EV, large EV and HRV presence higher than in most non-invasive test (NITs). In addition, it reports that the combination of Baveno VI criteria with SSM@100Hz for the diagnosis of HVR led to a spared EGD rate of 38.9%, without missing more than 5% of HRV, compared to Baveno VI criteria alone, having a spared EGD rate of 8.1%. This study has shown that the SSM is a non-invasive diagnostic tool useful to select patients at high risk for EV and PH, which could be later addressed to more invasive diagnostic investigations, such as EGD and HVPG measurement and to select patients for endoscopic screening of HRV. Finally, in the most recent EASL guidelines, the SSM is recommended as an additional NIT to further improve risk stratification and refine the risk of HRV.

However, NAFLD and obese patients were excluded from this study in order to work in the best standardized conditions. Then, with the NAFLD emergence worldwide, it appears to be needed to develop a probe dedicated to overweight and obese patients.
Consequently, the aim of this study is to develop the spleen examination measurement by FibroScan® for overweight or obese patients.

Study objective

Main objective : To develop a spleen examination dedicated to overweight or obese patients and assessits applicability.

Secondary objectives :
1. Develop a spleen exam dedicated to patients usually measured with the S+ probe and assess its applicability.
2. Optimize the available spleen exam dedicated to patients measured with the

M+ probe and assess its applicability.
3. Develop a spleen targeting tool (STT) and a measurement mode with automatic adaptation of depths (according to the patient's morphology) for the S+, M+ and XL+ spleen exams improving the applicability.

Study design

European, prospective, interventional, multicentre clinical investigation.

Study burden and risks

The additional constraint of the participation in this study is related to the condition of the examination, which is to be fasting for at least 3 hours before the FibroScan exam.

The risk to the use of the FibroScan is insignificant: no serious or non-serious adverse events have been reported since 2003. The FibroScan uses non-invasive and painless techniques, which is particularly adapted for early detection of chronic liver disease. The FibroScan is used in more than 80 countries around the world.

The adjustments made to the research device aim to collect the necessary information to develop the spleen examination of the FibroScan with the S+ and XL+ probes and to optimize the spleen examination with M+ probes. Patient participation will help researchers achieve the goals of this study with important new data to build and improve FibroScan® for spleen studies in more patients

In addition, developing such examination for overweight and obese patients as well as for children will give them the access to this non-invasive diagnostic technique detecting advanced chronic liver diseases.

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Children (2-11 years)
Elderly (65 years and older)
Babies and toddlers (28 days-23 months)
Newborns

Inclusion criteria

1. Adult or pediatric patient able to give written informed consent (parents/legal tutors in case of minor patients),
2. Patient affiliated to the healthcare system,
3. Adult or children patient followed for a liver disease, with or without splenomegaly and having a spleen to skin distance (SSD) measurement performed during the screening ultrasound exam.

Exclusion criteria

1. Vulnerable patient- other than pediatric patients
2. Patients with ascites

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	17-03-2023
Enrollment:	125
Type:	Actual

Medical products/devices used

Generic name:	Research FibroScan
Registration:	No

Ethics review

Approved WMO Date:	30-01-2023
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Approved WMO Date:	25-07-2023
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
ClinicalTrials.gov	NCT05122416
CCMO	NL81567.000.22