Evaluation of spleen stiffness applicability and utility in a tertiary hospital.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON24949

Source
NTR

Health condition

Portal hypertension; Liver cirrhosis; Liver test abnormalities; HBV; HCV; MALFD; Liver disease

Sponsors and support

Primary sponsor: Foundation for Liver and Gastrointestinal Research (SLO) c/o Department of Hepatology & Gastroenterology Erasmus MC, University Medical Center Rotterdam
Source(s) of monetary or material Support: Foundation for Liver and Gastrointestinal Research (SLO) c/o Department of Hepatology & Gastroenterology Erasmus MC, University Medical Center Rotterdam

Intervention

Outcome measures

Primary outcome

Correlation spleen stiffness measurement in relation to the absence or presence of portal hypertension

Secondary outcome

Predictors of spleen stiffness measurement success
Accuracy of spleen stiffness measurement
Predictors of accuracy of spleen stiffness measurement
Applicability of spleen stiffness measurement in patients with liver disease.

Study description

Background summary

To assess the correlation between spleen stiffness and portal hypertension we will prospectively include all patients who visited the liver ultrasound program of the Erasmus Medical Center, Rotterdam, with complete work-up according to standard care, including liver stiffness and spleen stiffness measurements.

Study objective

We aim to evaluate the full potential and applicability of SSM in patients with liver disease.

Study design

Prospective inclusion of patients from January 2021 and onwards.
The primary and secondary outcomes will be assessed at timepoint 0 (time of ultrasound/spleen stiffness measurement). The endpoints will be assessed with the use of spleen stiffness measurement (kPa) and ultrasound.

Contacts

Public
ErasmusMC
Marten Lantinga

0642844299
Scientific
ErasmusMC
Marten Lantinga

0642844299

Eligibility criteria

Inclusion criteria

Patients aged 18 years or older visiting the liver ultrasound unit of the ErasmusMC.

Exclusion criteria

Prior objection regarding the use of personal data for research

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	03-01-2021
Enrollment:	250
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Yes

Ethics review

Positive opinion

Date:	11-03-2021
Application type:	First submission

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
NTR-new	NL9369
Other	METC Erasmus MC : MEC-2021-0056

Study results