Global Research Initiative for Patients Screening on MASH

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

Summary

ID

NL-OMON56985

Source
ToetsingOnline

Brief title
GRIPonMASH

Condition

- Hepatic and hepatobiliary disorders

Synonym
fatty liver, liver fibrosis

Research involving
Human

Sponsors and support

Primary sponsor: Julius Clinical
Source(s) of monetary or material Support: METADEQ LIMITED,ECHOSENS,Europese Unie (IHI-JU;public-private partnership),NORDIC BIOSCIENCE A/S (NB) ,Novo Nordisk,ROCHE

Intervention

Keyword: FIB-4, FibroScan, liver fibrosis, MASLD

Outcome measures

Primary outcome

a. Steatosis stage deduced from controlled attenuation parameter (CAP) measurement with FibroScan; MASLD definition (CAP > 280 and 1 out of 5 cardiometabolic risk factors);

b. Fibrosis stage deduced from liver stiffness measurement (LSM) by vibration controlled transient elastography (VCTE) measurement with FibroScan

c. At-risk MASH deduced from FAST score

d. MASH diagnosis confirmed by histology (NAS/SAF criteria) upon liver biopsy;

c. Prevalences (see a. to d.) stratified per country;

d. Number of patients at-risk identified by FIB-4 in comparison to numbers found using LSM by VCTE with FibroScan measurements, and numbers found in combination.

Secondary outcome

1. Baseline clinical characteristics; genomic and proteomic analysis; metabolomic and lipidomic analyses; fluxomics analysis; prevalence comorbidities; prognostic factors;

2. PRO surveys at baseline and follow-up;

3. Revisited FibroScan measurements (CAP and LSM by VCTE) 12 weeks after of lifestyle recommendations;

4. Repeated CAP, LSM by VCTE and FAST measurement over time.

Study description

Background summary

Metabolic dysfunction-Associated Steatotic Liver Disease (MASLD) is estimated to be present in 30% of the world*s population, with serious complications and multiple associated co-morbidities. However, MASLD is relatively unknown and often diagnosed at a late stage. The current study will assist (primary) health care providers to implement the latest patient care pathway, as described by the European Association for the Study of Liver (EASL), to identify patients at-risk of severe MASLD and raise awareness. Identified patients with severe MASLD need to be monitored closely, they could be offered lifestyle intervention and they may be candidate for upcoming treatment options.

Study objective

The primary objective of this study is to implement a transmural patient care pathway as recommended by the EASL guideline of June 2024, in order to identify patients with MASLD and its progressive form of MASH in primary care centres (PCC) and clinics in 10 European countries.

Study design

10.000 high-risk patients (type 2 diabetes mellitus, metabolic syndrome, obesity or arterial hypertension) in 10 different European countries will be screened for the presence of MASLD, liver fibrosis and (at-risk) metabolic-dysfunction associated steatohepatitis (MASH) using at least two non-invasive tests (FIB-4 and FibroScan®). Additional published and exploratory non-invasive test will also be investigated. Blood samples and liver biopsy material will be collected following a predefined protocol. Genomic, proteomic, metabolomic, lipidomic and fluxomic studies will be applied to gain a better understanding of the pathophysiology of MASLD and to identify markers that will help to detect patients at-risk.

Study burden and risks

Patients are expected to have individual benefit from the study, as potential progressive forms of NAFLD will be diagnosed sooner and detailed follow-up and possibly treatment will be initiated within the patient care pathway. Most study procedures are non-invasive. A subset of the patients will undergo a liver biopsy. This is an invasive procedure, and it may be potential harmful as it may lead to bleeding, which would be controlled and treated according to good clinical practice.

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

- 18-75 year old;
- new or established diagnosis of at least 1 of the following 4 conditions:
type 2 diabetes mellitus, obesity, arterial hypertension or metabolic syndrome
(diagnostic criteria defined in protocol).

Exclusion criteria

- The patient is known with hepatitis B, C or HIV or any other liver condition
(like hemochromatosis, Wilson*s disease, sarcoidosis, etc);
- The patient is known with any other condition that may lead to liver fibrosis
or cirrhosis;

- The patient engages in (Excessive) alcohol use (defined as > 3 units/day in males [30 grams/day] and > 2 units/day in females [20 grams/day]);
- The patient has a history or evidence of any other clinically significant condition or planned or expected procedure that in the opinion of the Investigator, may compromise the patient*s safety or ability to be included in this study;
-The patient is an employee or contractor of the facility that is conducting the study or is a family member of the Investigator, sub-Investigator, or any Sponsor personnel;
- The patient is not able to understand the details of the protocol and/or is not able to provide written informed consent;
- The patient is pregnant or breastfeeding.
- The patient underwent bariatric surgery in the last 12 months.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	30-06-2023
Enrollment:	1000
Type:	Actual

Ethics review

Approved WMO

Date:	04-08-2022
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO

Date:	04-10-2023
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	29-08-2024
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	17-10-2024
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	06-11-2024
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NCT05651724
CCMO	NL81221.100.22