The search for biomarkers to enable detection and monitoring of disease progression from NAFLD to NASH and NASH itself; the Amsterdam NASH cohort

No registrations found.

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

Summary

ID

NL-OMON19935

Source
Nationaal Trial Register

Brief title
ANCHOR study

Health condition

NAFLD, NASH

Sponsors and support

Primary sponsor: Academic Medical Center (AMC), Amsterdam
Source(s) of monetary or material Support: Academic Medical Center (AMC), Amsterdam

Intervention

Outcome measures

Primary outcome

to identify and validate noninvasive diagnostic methods (imaging and molecular markers) in disease progression from NAFLD to NASH as well as progression of NASH itself

Secondary outcome

to apply a systems biology approach to identify the hierarchy of driving mechanisms (microbial and metabolic markers) involved in the conversion of NAFLD-NASH and NASH-cirrhosis after 5 years

Study description

Background summary

Our study aims to identify novel risk factors in subjects with hepatic steatosis, as well as to validate noninvasive imaging modalities, in order to better discern the patients who progress to NASH from non-progressing NAFLD patients. Our rigorous baseline biomarker validation against biopsy proven NAFLD-NASH progression over 5 years has the goal to reduce the need for future liver biopsies in NAFLD-NASH in the clinical setting.

Study objective

Since progression from NAFLD to NASH is associated with significantly increased risk of morbidity and mortality, there is a clinical imperative to identify the NAFLD patients that rapidly progress to NASH from those who will remain in the NAFLD stage, in order to better monitor these patients and to reduce their metabolic risk. Our study aims to identify novel risk factors in subjects with hepatic steatosis, as well as to validate noninvasive imaging modalities, in order to better discern the patients who progress to NASH from non-progressing NAFLD patients. Our rigorous baseline biomarker validation against biopsy proven NAFLD-NASH progression over 5 years has the goal to reduce the need for future liver biopsies in NAFLD-NASH in the clinical setting. As there are currently no registered treatment modalities for NASH besides dietary intervention, improved understanding of the pathophysiological mechanisms as well as their relationship to metabolic disturbances are of crucial importance to discover new diagnostic and therapeutical targets in NAFLD/NASH.

Study design

0 and 5 years

Intervention

Ultrasound guided liver biopsy

Contacts

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Eligibility criteria

Inclusion criteria

• Diagnosis of steatosis hepatis on ultrasound or by biopsy

• >18 years of age

• Transaminases ALAT and ASAT above upper limit (50U/L)

• BMI > 30 kg/ m^2

Exclusion criteria

• Abusive alcohol use (>20 IU/week)

• Hepatitis B and/or C

• Auto-immune hepatitis

• Wilsons disease/ alpha-1-antitripsine deficiency

• Hemochromatosis

• Bleeding disorder

• Use of drugs with a potential role in aggravation of pre-existing NAFLD

• Not able or willing to undergo MRI (for example claustrophobia, ICD, pacemaker)

• Diagnosis of liver cirrhosis and/or hepatocellular carcinoma

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other

Control: N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-04-2018
Enrollment:	1100
Type:	Anticipated

Ethics review

Positive opinion

Date:	03-04-2018
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 52739
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL7001
NTR-old	NTR7191
CCMO	NL63975.018.17
OMON	NL-OMON52739

Study results