Biomarkers and cardiovascular risk in disease models of non-alcoholic fatty liver disease

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1. To identify a biomarker of hepatic DNL in different disease models of NAFLD. 2. To assess the cardiovascular risk profile in the different disease models of NAFLD.

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

Summary

ID

NL-OMON48654

Source
ToetsingOnline

Brief title
Cardiovascular risk in NAFLD

Condition

- Hepatic and hepatobiliary disorders
- Inborn errors of metabolism
- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
fatty liver, nonalcoholic fatty liver disease (NAFLD)

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht
Source(s) of monetary or material Support: European Foundation for the Study of

Diabetes (EFSD)

Intervention

Keyword: biomarkers, cardiovascular disease, de novo lipogenesis, NAFLD

Outcome measures

Primary outcome

a set of candidate biomarkers of DNL measured in plasma

Secondary outcome

Secondary outcome: endothelial function (reactive hyperaemia peripheral

applanation tonometry, laser doppler flowmetry and plasma biomarkers)

Other parameters: hepatic fat accumulation (magnetic resonance spectroscopy)

and fat distribution (MRI)

Study description

Background summary

Epidemiological studies have demonstrated that non-alcoholic fatty liver disease (NAFLD) is associated with cardiovascular disease. Subsequent studies have suggested that hepatic de novo lipogenesis (DNL), i.e. de conversion of glucose to fat, is responsible for this association. However, there is currently no good biomarker of DNL that can be used to confirm this hypothesis in large epidemiological cohorts.

Study objective

1. To identify a biomarker of hepatic DNL in different disease models of NAFLD.
2. To assess the cardiovascular risk profile in the different disease models of NAFLD.

Study design

Observational study with a cross-sectional design.

Study burden and risks

The risks of this study are minimal, since no interventions are imposed. The only invasive test is blood withdrawal (150 ml in total; 165 ml for GSD1a patients), which is associated with minimal health risk. Subjects will undergo a screening for NAFLD, type 2 diabetes mellitus and cardiovascular risk, which may be of potential benefit.

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

Healthy individuals:
- age >< = 18 years, NAFLD disease models (n<=15 per group):

- diagnosis of glycogen storage disease 1a (GSD1a), familial partial lipodystrophy (FPL), maturity-onset diabetes of the young type 2 (MODY2) or abetalipoproteniemia/familial hypobetalipoproteinemia
- age >< = 18 years

Exclusion criteria

- Contraindications for MRI (i.e. claustrophobia, heart pacemaker or other electronic devices implanted in the body, history of collapse or seizure, or pregnancies < 12 weeks)
- Inability to give inform consent

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	25-05-2018
Enrollment:	85
Type:	Actual

Ethics review

Approved WMO

Date:	08-11-2017
Application type:	First submission

Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	19-04-2018
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL63134.068.17