Discovery of non-invasive biomarkers for immune-mediated liver diseases; AIH, DILI, NAFL and NASH.

Published: 13-12-2016 Last updated: 14-04-2024

The primary aim of this project is to discover new cellular (non-invasive) biomarkers for the diagnosis and monitoring of immune-mediated liver diseases. Secondly we aim to effectively differentiate AIH from DILI and NAFL from NASH.

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

Summary

ID

NL-OMON43305

Source ToetsingOnline

Brief title

Discovery of biomarkers for immune-mediated liver diseases.

Condition

- Hepatic and hepatobiliary disorders
- Autoimmune disorders

Synonym

autoimmune hepatitis, drug-induced liver injury, non-alcoholic fatty liver disease and nonalcoholic steatohepatitis

Research involving

Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum

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Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Hepatology, immune mediated, Immunophenotyping, Liver disease

Outcome measures

Primary outcome

Immunophenotype of intrahepatic and peripheral blood leukocytes.

Secondary outcome

Histology assessment of liver biopsy

Serology

Clinical Chemistry and Hematology laboratory results

Treatment regime

Occurrence of (serious) adverse events

Study description

Background summary

Diagnosis and monitoring of immune mediated liver diseases is generally dependent on surrogate biochemical markers which may not accurately reflect the actual liver status. Furthermore differentiation between these diseases often remains troublesome due to overlap in histological features. Identification of biomarkers, immunophenotyping of the intrahepatic immunology and improving diagnostics wil benefit

We hypothesize that the immune-mediated liver diseases AIH, DILI, NAFL and NASH have distinct immune fingerprints that can be identified by a comprehensive study of the cellular components of the immune system with multiparametric single cell analysis.

Study objective

The primary aim of this project is to discover new cellular (non-invasive) biomarkers for the diagnosis and monitoring of immune-mediated liver diseases.

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Secondly we aim to effectively differentiate AIH from DILI and NAFL from NASH.

Study design

Prospective observational cohort study

Study burden and risks

The burden of patients consist of an extra tube of blood drawn during 1 or 2 blood draws that are part of standard care. In addition, leftover liver tissue at diagnostic and follow-up liver biopsies will be used for intrahepatic immunophenotyping. In case there is no leftover liver tissue available, we will perform one extra biopsy to obtain liver tissue.

Contacts

Public

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years) Elderly (65 years and older)

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Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:

- * Indication for a biopsy for the diagnosis or monitoring of; AIH, DILI, NAFL or NASH
- * Eligible for liver biopsy
- * * 18 years old
- * Provide informed consent

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:

- * Contraindication for liver biopsy, determined by the clinician.
- * Current infectious disease.
- * Clinically relevant cardiovascular, pulmonary, or renal disease.
- * Medications with possible immune-modulating effects (e.g., steroids).
- * History of alcohol or drug abuse.

Study design

Design

Study type: Observational invasive		
Masking:	Open (masking not used)	
Control:	Uncontrolled	
Primary purpose:	Basic science	

Recruitment

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NL	
Recruitment status:	Pending
Start date (anticipated):	01-12-2016
Enrollment:	100
Туре:	Anticipated

Ethics review

Approved WMODate:13-12-2016Application type:First submissionReview commission:METC Amsterdam UMC

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 CCMO ID NL59115.029.16