Analysis of volatile organic compounds in exhaled air as a non-invasive biomarker for liver diseases

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To identify VOC profiles in exhaled air that are unique for specific liver diseases.

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

Summary

ID

NL-OMON36737

Source
ToetsingOnline

Brief title
Volatile organic compounds (VOCs) and liver diseases

Condition

- Hepatic and hepatobiliary disorders

Synonym
Hepatitis, liver diseases

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Liver diseases, Non-invasive tests, Volatile organic compounds (VOCs)

Outcome measures

Primary outcome

The primary outcome is to identify VOC profiles in exhaled air that are unique for specific liver diseases.

Secondary outcome

To compare the VOC profiles in exhaled air between patients with liver diseases and versus healthy controls.

To compare the VOC profiles before, during and after therapeutic interventions in various liver diseases (e.g. viral hepatitis, auto-immune hepatitis, NAFLD).

To compare VOC profiles with systemic inflammatory and oxidative stress markers.

To identify specific metabolites in VOC profiles to gain insight into the pathogenesis of liver diseases.

Study description

Background summary

Liver diseases such as non-alcoholic fatty liver disease (NAFLD), alcoholic liver disease (ALD) and viral hepatitis have the potential to progress to cirrhosis and finally hepatocellular carcinoma (HCC). Early diagnosis and treatment of liver diseases is important since progression is likely and is associated with significant morbidity and mortality. However, in daily clinical practice no specific and non-invasive biomarkers are used for the diagnosis and follow-up of patients with liver diseases.
It is known that different pathways of inflammation and oxidative stress and different metabolic processes are involved in the pathogenesis of liver diseases. Hence, patients with different liver diseases will form different

metabolites that will be excreted into the breath. These are called volatile organic compounds (VOCs). Analysis of VOCs in exhaled air has been reported to provide valuable information in patients with chronic obstructive lung disease (COPD) and inflammatory bowel disease (IBD). Also, in patients with liver diseases, exhaled VOCs have been detected and the presence of differences in VOC profiles among patients with different liver diseases has been suggested. We hypothesize that liver diseases with a different pathogenesis and etiology have different VOC profiles in exhaled air. Therefore, the analysis of VOC profiles in exhaled air can be useful for the diagnosis and follow-up.

Study objective

To identify VOC profiles in exhaled air that are unique for specific liver diseases.

Study design

This study is an observational study.

Study burden and risks

No side effects are expected from breath sampling.
No side effects are expected from sampling blood apart from the possible occurence of a small bruise.

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

- A clearly defined diagnosis of liver diseases based on laboratory, radiological and histological characteristics
- Age between 18 and 85 years

Exclusion criteria

- Inflammatory bowel diseases (IBD)
- Chronic obstructive lung disease (COPD), lung cancer, asthma
- Rheumatoid arthritis (RA)

Study design

Design

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

Recruitment

NL
Recruitment status: Recruiting

Start date (anticipated):	27-05-2011
Enrollment:	180
Type:	Actual

Ethics review

Approved WMO Date:	03-05-2011
Application type:	First submission
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
ClinicalTrials.gov	NCT01279356
CCMO	NL34991.068.10