

# The smell of a sick liver in primary sclerosing cholangitis

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To comprehensively profile the VOCs pattern in patients with PSC to get more insight in the etiology/pathogenesis of the disease, in particular the role of inflammation and gut microbiome.

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruiting
<b>Health condition type</b>	Gastrointestinal inflammatory conditions
<b>Study type</b>	Observational invasive

## Summary

### ID

NL-OMON48740

### Source

ToetsingOnline

### Brief title

VOCs in PSC

### Condition

- Gastrointestinal inflammatory conditions
- Hepatic and hepatobiliary disorders

### Synonym

PSC, Ulcerative colitis

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Academisch Medisch Centrum

**Source(s) of monetary or material Support:** Veni beurs

## Intervention

**Keyword:** PSC, UC, VOCs

## Outcome measures

### Primary outcome

VOCs pattern measured using Solid Phase Microextraction (SPME) in combination with Gas Chromatography coupled with time-of-flight-Mass Spectrometry (GC-tof-MS).

### Secondary outcome

Various metabolites and biomarkers in the blood and fecal samples.

As well as a one leaflet questionnaire containing questions about BMI, age, smoking & diet behavior and the Amsterdam Cholestatic Complaints Score and/or the Simple Clinical Colitis Activity Index.

## Study description

### Background summary

Primary Sclerosing Cholangitis (PSC) is a chronic cholestatic disease with multiple stenosis and segmental dilatations of the bile ducts. This liver disease is characterized by inflammation and fibrosis of both intrahepatic and extrahepatic bile ducts, leading to the formation of multifocal bile duct strictures. PSC ultimately can lead to cirrhosis, liver failure, malignancy and death (1). The etiology of PSC remains unknown.

In the current study the hypothesis is that that an on-going inflammatory stimulus, perhaps originating in the colon via \*leaky gut hypothesis\*, supports bile duct inflammation. Therefore, although PSC has a wide range of presentations, varying from no or little symptoms to severe cholestasis and/or portal hypertension, on-going inflammation is the common denominator. Therefore, integrated analysis of volatiles molecules in exhaled breath and feces in combination with fecal microbiome and blood plasma metabolites we hope to diagnose PSC at early, perhaps asymptomatic stage.

### Study objective

To comprehensively profile the VOCs pattern in patients with PSC to get more insight in the etiology/pathogenesis of the disease, in particular the role of inflammation and gut microbiome.

### **Study design**

Case-Control study in which exhaled VOCs patterns and fecal and blood metabolites of PSC patients (cases) are compared to UC patients (controls) and healthy controls.

### **Study burden and risks**

The risk is limited to the chance of development of an hematoma after vena puncture.

It is necessary to perform the current study in this population because it is the population of interest (PSC patients). To identify PSC specific biomarkers we have to compare the VOCs patterns of PSC patients to ulcerative colitis patients and to healthy controls.

## **Contacts**

### **Public**

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## **Trial sites**

### **Listed location countries**

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

Cases: Ulcerative colitis with or without PSC

Controls (UC): Ulcerative colitis

Controls (healthy): Able to give informed consent.

### Exclusion criteria

- \* Any disease compromising immune system (such as HIV positive status or patients after organ transplantations).
- \* Any other liver disease
- \* Active and untreated tuberculosis
- \* Use of chemotherapy agents

## 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:	Recruiting
Start date (anticipated):	19-11-2019
Enrollment:	265

Type: Actual

## Ethics review

Approved WMO	
Date:	20-11-2018
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	16-10-2019
Application type:	Amendment
Review 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	ID
CCMO	NL64879.018.18