Liver fat accumulation in inflammatory bowel disease

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To compare accumulation of liver fat (as measured using CAP) and liver fibrosis (as measured using fibroscan) between patients with quiescent and active inflammatory bowel disease

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Gastrointestinal inflammatory conditions
Study type	Observational non invasive

Summary

ID

NL-OMON44598

Source
ToetsingOnline

Brief title
IBD and fatty liver

Condition

- Gastrointestinal inflammatory conditions
- Hepatic and hepatobiliary disorders

Synonym
chronic bowel inflammation, inflammatory bowel disease

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: gut liver axis, inflammatory bowel disease, liver steatosis, NAFLD

Outcome measures

Primary outcome

Primary outcome measure will be CAP en Emed (Fibroscan measures for steatosis grade and fibrosis respectively)

Secondary outcome

Secondary study parameters: are to compare the relation between the following parameters and liver steatosis/ fibrosis:

1. Mediterranean Diet Serving Scale, as a measure of healthy food intake.

2. Food related quality of life (FR-QoL), disease-specific quality of life (sIBDQ) and general quality of life (SF-12)

3. Clinical activity of IBD (as assessed using symptom scores (Harvey-Bradshaw index (HBI) for CD activity and the MAYO score for UC activity), CRP and fecal calprotectin (the latter , as part of standard medical care)

4. Nutritional status and anthropometry (body weight, hand grip strength, waist-hip ratio)

5. Medication use

6. In patients with active disease at baseline, accumulation of liver fat will be compared between different types of medication used (steroids- mesalamine compounds- immune-modulators and biologicals)

Study description

Background summary

Increased occurrence of non-alcoholic fatty liver disease (NAFLD) is observed in patients with inflammatory bowel disease (IBD). Age, obesity, insulin resistance and other metabolic conditions are common risk factors, but recent data also point to IBD related factors such as disease activity, duration, steroid use and prior surgical intervention, in the development of NAFLD. Overall chronic inflammation, impaired intestinal barrier function and microbial disturbances could play an important role in both IBD and NAFLD pathogenesis. Additionally, commonly used immunosuppressive medication in the treatment of IBD could potentially cause hepatic toxicity, but no conclusive evidence exists linking them to the development of hepatic steatosis. Furthermore, there are no data on the impact of fatty liver on IBD-therapy and prognosis in patient with co-existent diseases. In this study, we aim to compare the effect of active and quiescent disease on liver fat and liver fibrosis.

Study objective

To compare accumulation of liver fat (as measured using CAP) and liver fibrosis (as measured using fibroscan) between patients with quiescent and active inflammatory bowel disease

Study design

This is an observational cohort study on accumulation of liver fat and development of liver fibrosis in patients with active and queiescent inflammatory bowel disease.

Study burden and risks

There is no additional risk involved. Treatment and follow-up will be according to standard medical care. Participation will only involve filling in questionnaires and undergoing a Fibroscan (non-invasive test, www.fibroscan.com) at baseline and after regular follow-up clinical visits.

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

Patient age >18 years
A confirmed diagnosis of either crohns disease, ulcerative colitis or IBD-unclassified.

Exclusion criteria

Patients unable or unwilling to provide informed consent

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-06-2017
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO

Date:	30-05-2017
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL61647.058.17