FIbroscan To detect LIVER fibrosis in patients with inflammatory bowel disease receiving long-term thiopurine therapy

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21349

Source
Nationaal Trial Register

Brief title
FIT-LIVER

Health condition

Inflammatory Bowel Disease, thiopurines, hepatotoxicity, hepatotoxiciteit, liver fibrosis, lever fibrose

Sponsors and support

Primary sponsor: VU University Medical Center
Source(s) of monetary or material Support: None

Intervention

Outcome measures

Primary outcome

Liver stiffness score (Metavir), F0-F4

Secondary outcome

N/A

Study description

Background summary

Inflammatory Bowel Disease (IBD) comprises two chronic conditions of the gastrointestinal tract, namely Crohn's disease and ulcerative colitis. These diseases are characterized by episodes of remissions and relapses, causing significant decreases in quality of life and thus emphasizing the need of drugs maintaining remission. The first-step in maintaining remission is the administration of thiopurines (i.e. azathioprine and mercaptopurine). [Dignass, 2010; 2012] One of the concerns of this therapy is the alleged risk of associated liver pathology. [Dubinsky, 2003; Vernier-Massouille, 2007].

According to a database study in 2007, liver test (LT) abnormalities occur in up to 16% of IBD-patients, regardless of therapy or concomitant diagnoses. Interestingly, only 42% of these LT abnormalities could be linked to thiopurine use, leaving at least 58% of LT abnormalities caused by other reasons than thiopurine therapy. [Gisbert, 2007].

In other literature reports, thiopurine use is linked to various liver abnormalities, such as sinusoidal obstructive syndrome (SOS), nodular regenerative hyperplasia (NRH), liver cirrhosis, liver fibrosis or non-cirrhotic portal hypertension (NCPH). [Dubinsky, 2003; Vernier-Massouille, 2007; Suárez-Ferrer, 2015; Jharap, 2015]. These diagnoses were assessed primarily by liver biopsy, which is an invasive procedure.

Using a Fibroscan, fibrosis of the liver might be measured using a non-invasive procedure. In previous studies, fibroscan measurements seemed to correlate with results from liver biopsies in a large number of patients [Muñoz, 2009; Goyal, 2013].

Study objective

Inflammatory Bowel Disease patients using thiopurines are at higher risk of developing liver abnormalities than IBD patients without thiopurine exposure.

Study design

t=0

Intervention

Fibroscan: Also called transient elastography, used to assess liver stiffness (measured in kPa) without invasive investigation.

Contacts

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Eligibility criteria

Inclusion criteria

Adult patients (>18 y/o)

Diagnosed with inflammatory bowel disease (i.e. Crohn’s disease, ulcerative colitis or IBD unclassified)

Exclusion criteria

Concomitant known liver pathology (e.g. viral hepatitis, liver cancer, liver cirrhosis, liver fibrosis)

Study design

Design

Study type:	Interventional
Intervention model:	Other

Control: N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2016
Enrollment:	0
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

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
NTR-new	NL5770
NTR-old	NTR5924

Register ID

Other	Health and Disability Ethics Commitee in Nieuw-Zeeland// METC VU : 16/CEN/81 // 2016.316

Study results