

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

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

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON21349

Bron

Nationaal Trial Register

Verkorte titel

FIT-LIVER

Aandoening

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

Ondersteuning

Primaire sponsor: VU University Medical Center

Overige ondersteuning: None

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Liver stiffness score (Metavir), F0-F4

Toelichting onderzoek

Achtergrond van het onderzoek

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].

Doel van het onderzoek

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

Onderzoeksopzet

t=0

Onderzoeksproduct en/of interventie

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

Contactpersonen

Publiek

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Adult patients (>18 y/o)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type: Interventie onderzoek

Onderzoeksmodel: Anders

Controle: N.v.t. / onbekend

Deelname

Nederland

Status: Werving nog niet gestart

(Verwachte) startdatum: 01-09-2016

Aantal proefpersonen: 0

Type: Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort: Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL5770
NTR-old	NTR5924
Ander register	Health and Disability Ethics Committee in Nieuw-Zeeland// METC VU : 16/CEN/81 // 2016.316

Resultaten