Lipid changes in patients with active ulcerative colitis treated with either tofacitinib or infliximab

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Treatment with tofacitinib or infliximab show similar changes in lipid and lipoprotein levels in patients with ulcerative colitis

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON23533

Bron
Nationaal Trial Register

Aandoening

Ulcerative colitis
Lipids
Tofacitinib
Infliximab

Ondersteuning

Primaire sponsor: Erasmus Medical Center
Overige ondersteuning: Governmental funding by the Ministry of Education, Culture and Science

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Changes in HDL- and LDL-cholesterol concentrations after tofacitinib and infliximab induction therapy of 8 weeks

Toelichting onderzoek

Achtergrond van het onderzoek

Recently tofacitinib is registered for the treatment of moderate to severe ulcerative colitis. In the tofactinib clinical development program (OCTAVE), mild elevations in serum lipid levels in a proportion of those receiving tofacitinib were described without further side effects. Mild alterations in the lipid profile are also observed in patients with inflammatory bowel disease (IBD) treated with infliximab (IFX). Although an overall increase in total cholesterol and low density lipoprotein cholesterol (LDL-C) is unwanted, an increase in high density lipoprotein cholesterol (HDL-C) as a result of treatment might protect against cardiovascular events. Moreover, these findings are consistent with the previously observed inverse relationship between active inflammation and serum lipid levels in chronic inflammatory disease including rheumatoid arthritis (RA) and psoriatic arthritis (PA). The mechanisms by which the inflammatory process can lead to these lipid changes are not fully understood.

Doel van het onderzoek

Treatment with tofacitinib or infliximab show similar changes in lipid and lipoprotein levels in patients with ulcerative colitis

Onderzoeksopzet

Infliximab: weeks 0, 5, 8, 21, 52

Tofacitinib: weeks 0, 5, 8, 21, 34, 47, 52

Onderzoeksproduct en/of interventie

Randomization in a 1:1 to either:

- tofacitinib arm: induction therapy 10mg oral tablets twice daily during 8 weeks and maintenance therapy 5mg tablets twice daily until week 52

- infliximab arm: induction therapy with infliximab infusions 5mg/kg on week 0, 2 and 6 and maintenance therapy of infliximab infusions 5/mg/kg every 8 weeks

Additional interventions:

- vena punction for serum sample analyses

- home test for stool sampling

- questionnaires

(- preferably, endoscopy)

Contactpersonen

Publiek

Wetenschappelijk

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- aged 18 years or older

- previous diagnosis with ulcerative colitis (UC) of at least 3 months

- at least moderately active UC defined as SCCAI-score ¡Ý5 or FCP >150 ug/g

- 5-ASA or thiopurine refractory or intolerant disease

- BMI 20-35 kg/m2

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- absence written informed consent

- imminent need for in-hospital treatment

- concomitant use of oral of intravenous corticosteroids (except locally administered budesonide down tapering)

- current or previous treatment with a biological agents (except history of infliximab use with good clinical response, discontinued at least 12 weeks prior to randomization)

- concomitant use of lipid-regulating agents, ormonal forms of contraception, isotretinoin, supplements with plant sterols, stanols or cholestin

- current or previous treatment with investigational drugs

- pregnancy or lactation

- concomitant disease or abnormalities (pancytopenia, kidney or liver failure, acute/latent/inadequately treated infection, hyperlipidemia, hypoalbuminemia, cardiopulmonary disease, endocrine disease)

- other signficant illnesses (e.g. malignancy, immunodeficiency syndromes, psychiatric illness)

- impossibility to measure outcomes (plannen relocation, language issues, short life expectancy)

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-12-2018
Aantal proefpersonen:	40
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing
Soort: Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 55536
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL7377
NTR-old	NTR7585
CCMO	NL67752.078.18
OMON	NL-OMON55536

Resultaten