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

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON23533

Source
Nationaal Trial Register

Health condition

Ulcerative colitis
Lipids
Tofacitinib
Infliximab

Sponsors and support

Primary sponsor: Erasmus Medical Center
Source(s) of monetary or material Support: Governmental funding by the Ministry of Education, Culture and Science

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

- Changes in total cholesterol, triglycerides, apo-A1, apo-B, Lp(a) after induction therapy

- Changes in total cholesterol, HDL, LDL, triglycerides, apo-A1, apo-B, Lp(a) after maintenance therapy

- Correlation between lipid changes and inflammatory status

- Shifts in density of lipoproteins and their subfractions with alterations in their composition and functioning

- Effect of treatment on HDL2 and HDL3 composition and functioning (including anti-inflammatory function)

- Effect of treatment on cholesterol homeostasis (cholesterol absorption, synthesis, bile acid synthesis and oxysterol formation)

- Mechanisms underlying changes in lipoproteins focussing on cholesterol metabolism, inflammation, insulin resistance and bile acids

- Difference in change in lipid profile between tofacitinib and infliximab treatment

- Difference in treatment efficacy with regard to clinical, biochemical and endoscopic response

- Difference in safety profile measured by adverse events (AEs)

Study description

Background summary

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.

Study objective

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

Study design

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

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

Intervention

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)

Contacts

Public

Scientific

Eligibility criteria

Inclusion criteria

- 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

Exclusion criteria

- 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)

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-12-2018
Enrollment:	40
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

ID: 55536
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

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

Study results