

Lipid changes after induction therapy in patients with Inflammatory Bowel Disease: effect of different drug classes and inflammation

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON22770

Source

Nationaal Trial Register

Brief title

CIAT

Health condition

Inflammatory bowel disease

Sponsors and support

Primary sponsor: Erasmus Medical Center (investigator-initiated)

Source(s) of monetary or material Support: Not applicable

Intervention

Outcome measures

Primary outcome

Lipid changes after induction therapy (total cholesterol, HDL-c, LDL-c, triglycerides,

apolipoprotein-B and lipoprotein a)

Secondary outcome

Association with drug class and inflammation

Study description

Background summary

Prospective, observational cohort study in patients with inflammatory bowel disease (IBD) assessing lipid changes after 10-week induction therapy with corticosteroids, thiopurines, methotrexate, anti-TNF α agents, vedolizumab, ustekinumab and tofacitinib

Study objective

Lipid changes are a more general consequence of improved systemic/intestinal inflammation

Study design

Baseline and week 10 (+- scope of 2 weeks)

Contacts

Public

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Scientific

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Eligibility criteria

Inclusion criteria

ii) IBD diagnosis, ii) age =>17 years, iii) starting systemic registered IBD drug therapy

Exclusion criteria

i) the use of lipid lowering drugs (with the exception of cholestyramine on stable dose throughout the study), ii) supplements containing plant sterols/stanols or cholestin, iii) pregnancy, iv) a history of liver transplantation

Study design

Design

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

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	01-04-2019
Enrollment:	20
Type:	Actual

IPD sharing statement

Plan to share IPD: Yes

Plan description

The data that supports the findings of this study are available in the (supplementary) material of this article. The IPD that support the findings of this study are available from the corresponding author upon reasonable request, including a research protocol. Data Transfer Agreement (DTA) needs to be drawn, checked by legals and signed by both parties. Only de-identified study data will be shared. Mechanism of data sharing will be in consultation with Erasmus MC's data protection officer.

Ethics review

Positive opinion

Date: 22-10-2021

Application type: First submission

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	NL9844
Other	METC Erasmus MC : MEC-2019-0073

Study results