

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

No registrations found.

<b>Ethical review</b>	Positive opinion
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	-
<b>Study type</b>	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 $\alpha$  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**

Erasmus Medical Center  
Jasmijn Sleutjes

0627256693

### **Scientific**

Erasmus Medical Center  
Jasmijn Sleutjes

0627256693

## **Eligibility criteria**

## Inclusion criteria

ii) IBD diagnosis, ii) age  $\geq 17$  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