Adjusting infliximab dose in patients with inflammatory bowel disease, based on blood levels.

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27672

Source
NTR

Brief title
ILIST

Health condition

Inflammatory Bowel Disease, in remission with infliximab treatment.

Sponsors and support

Primary sponsor: Erasmus MC Rotterdam
Source(s) of monetary or material Support: N/A

Intervention

Outcome measures

Primary outcome

Number of patients in remission, 6 months after dose adjustment of IFX
Efficacy of IFX maintenance therapy dosed at 3mg/kg in IBD

Secondary outcome

Number of relapses, defined by increase of fecal calprotectin and/or CRP and clinical activity, in patients with and without dose adjustments

Number of patients in remission at 12 months

Cost-effectiveness of IFX dose adjustments

Study description

Background summary

N/A

Study objective

Infliximab dose can be tailored based on individual trough levels.

Study design

Follow-up up to 64 weeks.

Intervention

IFX trough levels are measured in IBD patients in long term remission. Based on IFX trough levels, the IFX dose may be adjusted. The IFX dosing interval does not change.

If IFX trough levels are high (<3µg/mL), the IFX dose is reduced to 3mg/kg in case of 5mg/kg, or to 5 mg/kg in case of 10 mg kg.
If IFX trough levels are normal (0 – 3 µg/mL), the IFX dose remains stable.

Contacts

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Eligibility criteria

Inclusion criteria

1. Age 18-70

2. Written informed consent

3. Patients with inflammatory bowel disease (IBD) treated with infliximab (IFX)

4.. In clinical remission for 18 months after initiation of infliximab

5. Fecal calprotectin < 200 µg/g

6. Permitted concomitant therapy: aminosalicylates, thiopurines and methotrexate at stable dose for at least 12 weeks

Exclusion criteria

1. Concomitant corticosteroid usage

2. Pregnancy or lactation

3. Other significant medical illness that might interfere with this study (such as current malignancy, immunodeficiency syndromes and psychiatric illness)

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial
Masking:	Double blinded (masking used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-10-2013
Enrollment:	40
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

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	NL3905
NTR-old	NTR4067

Register	ID
Other	: 2013-002651-15

Study results

Summary results
N/A