Biomarkers predicting the effect of anti-TNF treatment in pediatric and adult inflammatory bowel disease.

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Main objective: To validate novel biomarkers that can predict (non-)response to anti-TNF induction treatment in pediatric and adult IBD patients.Secondary objectives: To accurately describe pharmacokinetics of IFX and ADA in pediatric and adult IBD...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Gastrointestinal inflammatory conditions
Study type	Observational non invasive

Summary

ID

NL-OMON39856

Source
ToetsingOnline

Brief title
Biomarkers of anti-TNF treatment in IBD

Condition

- Gastrointestinal inflammatory conditions

Synonym
Inflammatory Bowel Diseases

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W,MSD geeft benchfee ondersteuning

Intervention

Keyword: Anti-TNF, Biomarkers, IBD

Outcome measures

Primary outcome

1. pre-treatment serum level of endogenous anti-TNF in relation to initial

response (= clinical remission) or non-response at week 8 in the two age

groups.

2. RNA expression profiles in relation to initial response (= clinical

remission) or non-response at week 8 in the two age groups

Secondary outcome

N/A

Study description

Background summary

Anti-TNF treatment (infliximab (IFX), adalimumab (ADA)) has become standard therapy for refractory pediatric and adult Crohn*s disease (CD) patients, and is used for the induction (primary response) and maintenance of remission. When effective, clinical and endoscopic remission is reached within weeks. However, primary non-response is observed in 20% of pediatric patients, and in 40% of adult CD patients, suggesting a more robust acute response to anti-TNFa therapy in children as compared to adults. During maintenance treatment, 60 - 80% of patients have secondary loss of response, necessitating dose adjustments to maintain clinical response. Anti-TNF treatment is also increasingly used in ulcerative colitis, and has been shown to induce remission in active disease. For UC, the comparison between the efficacy in children versus adults is more difficult to report as studies in children are scarce. Anti-TNF treatment is associated with rare but potentially fatal side effects, infusion reactions, and is an expensive treatment. To avoid overtreatment it is necessary to early identify non-responders to treatment, and therefore it is important to develop predictive biomarkers of treatment response.

Study objective

Main objective: To validate novel biomarkers that can predict (non-)response to anti-TNF induction treatment in pediatric and adult IBD patients.
Secondary objectives: To accurately describe pharmacokinetics of IFX and ADA in pediatric and adult IBD patients; to evaluate differences between pediatric and adult IBD regarding anti-TNF treatment behavior and expression of biomarkers; to evaluate the disease course in non-responders to anti-TNF induction therapy.

Study design

Single-center, prospective cohort study, with a follow-up period of 1 year.

Study burden and risks

Patients will not benefit from participating in this study. Study visits will coincide with regular visits to the infusion department and/or outpatient clinic, and extra blood will be withdrawn during routine blood tests only, resulting in a minimal extra burden for patients. In addition buccal epithelium will be collected. Our study population will partly consist of pediatric patients, as pediatric IBD seems to represent a specific group of IBD patients with a distinct disease phenotype and clinical presentation compared with adults.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Children (2-11 years)
Elderly (65 years and older)

Inclusion criteria

- anti-TNF naïve CD patients (6 years and older) who initiate anti-TNF treatment (infliximab (IFX) or adalimumab (ADA)) because of active luminal disease, failing treatment with immunomodulators and corticosteroids
- anti-TNF naïve UC patients (6 years and older) who initiate anti-TNF treatment (IFX or ADA) because of active disease despite corticosteroid treatment or because of failing of immunomodulators treatment
- anti-TNF naïve CD or UC patients (6 years and older) who initiate anti-TNF treatment (IFX or ADA) because of intolerance to treatment with immunomodulators or corticosteroids

Exclusion criteria

- IBD patients who initiate IFX or ADA immediately after diagnosis
- presence of severe perianal disease as primary indication to start anti-TNF treatment
- age younger then 6 years when anti-TNF maintenance treatment is initiated

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped

Start date (anticipated):	22-11-2013
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO Date:	03-10-2013
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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
CCMO	NL42736.078.13