# Measuring infliximab and adalimumab blood levels in IBD patients, prospective observations from a single center compared to a time period before regular use of these measurements.

No registrations found.

| | |
|---|---|
| **Ethical review** | Not applicable |
| **Status** | Other |
| **Health condition type** | - |
| **Study type** | Observational non invasive |

## Summary

### ID

NL-OMON29021

**Source**
Nationaal Trial Register

**Brief title**
TDM of TNF-alpha blockers in IBD

**Health condition**

Inflammatory bowel diseases, IBD, inflammatoire darm ziekten, Crohn's disease, Ziekte van Crohn, ulcerative colitis, colitis ulcerosa, IBD-U, IBD-unclassified, biologicals, TNFalpha blockers, anti-TNF-alfa, infliximab, IFX, adalimumab, ADM, therapeutic drug monitoring, TDM, trough levels, medicatiespiegels, dalspiegels.

### Sponsors and support

**Primary sponsor:** Noordwest Ziekenhuisgroep
**Source(s) of monetary or material Support:** Noordwest Ziekenhuisgroep
The project leader received an educational grant from Janssen-Cilag B.V.

## Intervention

## Outcome measures

### Primary outcome

To explore the proportion of patients needing rescue therapy in the form of steroids, surgery and/or discontinuation or switch of the TNF-alpha blocker due to refractory disease in a one year period

### Secondary outcome

• Descriptive data per IFX or ADM on the number of trough level/ADA measurements and its values and indications for measurement. A comparison of these values between the three major reasons for TDM: loss of response or before intended treatment alterations or after remission induction in the fixed one year cohorts.

• For participants commencing therapy during the study periods, follow-up time for registration of events will be extended to include one full year of therapy.

• We will gather information on the effect of TDM on treatment decisions: on dose alterations or drug discontinuation and for the prospective cohort on adherence to the uniform treatment algorithm.

• Exploratory IBD related costs, including serum trough measurement, IBD medication costs (for IFX corrected for different costs related to originator/biosimilar), hospitalization, medical visits because of suspected disease flare and diagnostics utilized to analyse possible disease flare will be compared.

• Lastly the number of flares defined by physician assessment in combination with at least one of two biomarkers elevated: C-reactive protein (CRP) > 5 mg/l and faecal calprotectin (FCP) > 150 mg/kg indication disease activity or defined by endoscopy (physician assessed).

• Differences between IBD sub types will be explored

# Study description

### Background summary

This investigator-initiated prospective observational cohort study will explore the differences between two cohorts:

Prospective cohort: A structured format for TDM-assisted, clinical decision making in regard

to IFX and ADM for IBD was implemented as standard care in our hospital group. In this strategy, serum trough levels of both biologicals will be measured at pre-specified moments to structure the use of these expensive therapies: after remission induction, in case of a proven disease flare or when an alteration in treatment regimen of the biological or immunomodulatory drug is considered. An algorithm for interpretation of drug levels and advisory treatment alteration is given for each specific measurement occasion. These strategies were developed by reviewing available literature on the application of TDM under different circumstances. An overview of the newly implemented strategy can be requested from the corresponding author. The strategy combines TDM with three IBD-specific patient-reported outcome measures, translated and validated for Dutch IBD patients. These measures were added to systematically compare patients IBD related symptoms in relation to TDM and biomarkers.

Historical cohort: in a timeframe where infliximab and adalimumab had an established place in the treatment of IBD, but dose alterations and treatment optimizations were based on clinical signs and symptoms. TDM for the analysis of anti-drug antibodies was freely available, but not part of standard care. The care provided in this cohort is in accordance with the current national treatment guidelines for IBD.

**Study objective**

Proactive and reactive trough level measurements of TNFalpha blockers are useful in standard care by aiding an individualized treatment strategy, preventing loss of efficacy and reducing disease flares, while being more cost-effective than symptom-based treatment alterations.

**Study design**

Data from both cohorts will cover one year, the historical cohort from 01-01-2016 up to 01-01-2017 and the prospective cohort from 01-09-2018 up to 01-09-2019. For both cohorts, patients initiating infliximab or adalimumab therapy during these periods, data collection will cover a year onwards from starting therapy. As patients cannot all be included on the actual day of commencing the prospective observational study, we will ask permission to collect any data from 01-09-2018 up to consent, retrospectively. Data on the historical cohort will be collected in the time period of the prospective cohort. We aim to start inclusion from 01-11-2018 onwards. Data analysis and manuscript formation will commence starting November 2019 and are estimated to take up to the November 2020.

**Intervention**

None

# Contacts

**Public**

**Scientific**

# Eligibility criteria

## Inclusion criteria

For the historical cohort:

- All patients who were 18 years and older on 01-01-2016 and no longer being cared for by our paediatricians

- Diagnosed with Crohn’s disease, ulcerative colitis or IBD-unclassified

- Received infliximab or adalimumab in any dosage between 01-01-2016 and 01-01-2017

For the prospective cohort:

- All patients who are 18 years and older on 01-09-2018 and no longer being cared for by our paediatricians

- Diagnosed with Crohn’s disease, ulcerative colitis or IBD-unclassified

- Being treated with infliximab or adalimumab in any dose on 01-09-2018 or being put on them after that date up to 01-09-2019

## Exclusion criteria

-Any IBD-patient (who was) participating in a clinical trial for one of these biologicals that dictated/s an alternative treatment regimen than was/is used in clinical practice.

- Any IBD patient whose treatment indication for infliximab or adalimumab is/was not primarily for IBD during the study periods (such as rheumatoid arthritis or psoriasis).

# Study design

## Design

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|---|---|
| Study type: | Observational non invasive |
| Intervention model: | Other |
| Masking: | Open (masking not used) |
| Control: | N/A , unknown |

## Recruitment

NL

| | |
|---|---|
| Recruitment status: | Other |
| Start date (anticipated): | 01-11-2018 |
| Enrollment: | 275 |
| Type: | Unknown |

# 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 | NL7354 |
| NTR-old | NTR7562 |
| Other | Noordwest ziekenhuisgroep : L018-078 |

# Study results

**Summary results**
Intentions are publication in an international peer reviewed scientific magazine.