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.

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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-...

Ethische beoordeling	Niet van toepassing
Status	Anders
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON29021

Bron
Nationaal Trial Register

Verkorte titel
TDM of TNF-alpha blockers in IBD

Aandoening

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.

Ondersteuning

Primaire sponsor: Noordwest Ziekenhuisgroep
Overige ondersteuning: Noordwest Ziekenhuisgroep
The project leader received an educational grant from Janssen-Cilag B.V.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

None

Contactpersonen

Publiek

Wetenschappelijk

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

-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).

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Anders
(Verwachte) startdatum:	01-11-2018
Aantal proefpersonen:	275
Type:	Onbekend

Ethische beoordeling

Niet van toepassing
Soort: Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL7354
NTR-old	NTR7562
Ander register	Noordwest ziekenhuisgroep : L018-078

Resultaten

Samenvatting resultaten
Intentions are publication in an international peer reviewed scientific magazine.