Pharmacokinetic study of Infliximab in young IBD patients below the age of 9 years to construct a dosing algorithm model for IFX

Gepubliceerd: 12-09-2015 Laatst bijgewerkt: 18-08-2022

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 and maintenance of remission. When effective, clinical and...

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON23711

Bron
NTR

Verkorte titel
RAPID - IBD

Aandoening

Inflammatory Bowel Disease, pediatric, anti-TNF therapy, IBD
Kinderen, chronische darmziekten

Ondersteuning

Primaire sponsor: Erasmus Medical Center, Rotterdam
Overige ondersteuning: Erasmus Medical Center, Rotterdam

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Clinical efficacy of IFX treatment in pediatric IBD patients (¡Ü 9 years) in relation to
- Antropometric data
- Clinical data
- Pharmacokinetics (including the presence of antibodies to IFX)
- Safety
o Number of (serious) adverse events

Toelichting onderzoek

Doel van het onderzoek

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 and maintenance of remission. When effective, clinical and endoscopic remission is reached within weeks. In ulcerative colitis anti-TNF treatment is also increasingly used, and has been shown to induce remission in active disease.
Early IFX pharmacokinetic (PK) data showed a consistent trend towards lower mean serum IFX concentrations after a single dose of 5 and 10 mg/kg in pediatric compared to adult CD patients. Over time some papers have suggested IFX PK are not statistically different between pediatric and adult CD or UC patients. However recent data suggests decreased sustained IFX efficacy in early-onset IBD patients (< 8 years), specifically in children 5 years old and younger.
Alternate absorption, distribution, metabolism and excretion between children and adults may all play a role.(Shi and Derendorf 2010). The exact underlying mechanisms are currently incompletely understood. Our primary aim is to assess pharmacokinetics of IFX, based on existing therapeutic drug monitoring (TDM) data, in relation to efficacy and safety in pediatric IBD patients below the age of 9 years. Our secondary aim is to construct a dosing guideline based on these retrospectively collected data for more accurate IFX dosing.

Onderzoeksopzet

Not Applicable

Onderzoeksproduct en/of interventie

Retrospective collection of data

Contactpersonen

Publiek

L. de Ridder
Wytemaweg 80

Rotterdam 3015 CN
The Netherlands
tel 010 703 60 49

Wetenschappelijk

L. de Ridder
Wytemaweg 80

Rotterdam 3015 CN
The Netherlands
tel 010 703 60 49

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Pediatric IBD patients (¡Ü 9 years) who have initiated IFX treatment because of active luminal disease, failing treatment with immunomodulators and corticosteroids

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- IFX treatment started for a condition other than IBD

- Missing data on IFX dosing or levels

- Age > 9 years when IFX treatment was initiated

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-10-2015
Aantal proefpersonen:	50
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	12-09-2015
Soort:	Eerste indiening

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	NL5390
NTR-old	NTR5491
Ander register	Erasmus MC Rotterdam : MEC-2015-503

Resultaten