Increasing time between adalimumab injections in IBD patients.

Gepubliceerd: 30-01-2014 Laatst bijgewerkt: 13-12-2022

Previous studies have shown that the half life of adalimumab increases to up to 21 days, after several doses have been administered. As such it seems possible to increase the dosing interval from 14 days to 21 days, in patients IBD in long term...

Ethische beoordeling	Niet van toepassing
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON20310

Bron
NTR

Verkorte titel
LADI study.

Aandoening

Crohn's Disease
Ulcerative Colitis
Inflammatory Bowel Disease
Adalimumab

Ondersteuning

Primaire sponsor: Erasmus MC
Overige ondersteuning: not applicable

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Number of patients in remission, 24 weeks after dose adjustment of adalimumab

Toelichting onderzoek

Achtergrond van het onderzoek

Single center, randomized, controlled, open label trial with two treatment arms.

Rationale:

Healthcare costs in IBD are mainly driven by medication costs, with anti-TNF alfa therapies making up the bulk of these costs. If it is possible to safely lengthen the adalimumab dosing interval from 2 weeks to 3 weeks, this would result in significant reduction of medication and total healthcare costs.

Objective: To assess the safety of lengthening the adalimumab dosing interval from 2 to 3 weeks, in patients with Crohn’s disease or ulcerative colitis in long term (6 months) remission.

Doel van het onderzoek

Previous studies have shown that the half life of adalimumab increases to up to 21 days, after several doses have been administered.
As such it seems possible to increase the dosing interval from 14 days to 21 days, in patients IBD in long term remission.

Onderzoeksopzet

Study duration per patient: 24 weeks

Follow-up visits every 6 weeks.

Onderzoeksproduct en/of interventie

Intervention: adalimumab 40mg every 21 days
Control: adalimumab 40mg every 14 days

Contactpersonen

Publiek

Erasmus MC
Postbus 2040
M. Lie
Rotterdam 3000 CA
The Netherlands

Wetenschappelijk

Erasmus MC
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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Age 18 or older.

Written informed consent.

Previous diagnosis of ileocolonic Crohn’s disease or ulcerative colitis

In sustained clinical remission for at least 6 months whilst being treated with adalimumab

Adalimumab dosed at 40mg, once every 2 weeks

Full clinical response and disease control, defined as:

-Absence of intestinal or extra-intestinal symptoms, as judged by both patient and physician

-Fecal calprotectin < 200 ìg/g and CRP within normal range

-Full endoscopic remission (no ulcera) assessed at least within 12 months before inclusion

Permitted concomitant therapy: aminosalicylates, azathioprine, 6-mercatopurine and methotrexate at stable dose for 12 weeks

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Concomitant corticosteroid usage

Imminent need for IBD-related surgery

Actively draining perianal fistula

Pregnancy or lactation

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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-04-2014
Aantal proefpersonen:	72
Type:	Verwachte startdatum

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	NL4443
NTR-old	NTR4566
Ander register	: -

Resultaten

Samenvatting resultaten

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