

# Azathioprine maintenance treatment versus infliximab maintenance treatment in Crohn's disease patients in remission (Azorix trial)

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Immuune suppressie therapie (azathioprine of 6-Mercaptopurine) onderhoud therapie is zo effectief als infliximab onderhoud therapie na remissie-inductie met gecombineerde infliximab/immuun suppressie therapie voor ten minste 6 maanden.

<b>Ethische beoordeling</b>	Positief advies
<b>Status</b>	Werving gestart
<b>Type aandoening</b>	-
<b>Onderzoekstype</b>	Interventie onderzoek

## Samenvatting

### ID

NL-OMON21255

### Bron

NTR

### Verkorte titel

Azorix trial

### Aandoening

Crohn's disease in remission

### Ondersteuning

**Primaire sponsor:** Academic Medical Center (AMC)

**Overige ondersteuning:** No funding source

### Onderzoeksproduct en/of interventie

## **Uitkomstmaten**

### **Primaire uitkomstmaten**

The occurrence of relapse - defined as a disease activity with a CDAI score greater than 150 - during the 12 months follow-up period.

## **Toelichting onderzoek**

### **Achtergrond van het onderzoek**

Crohn disease (CD) patients that have a flare of disease activity while on immune suppressive (IS) medication (such as azathioprine (AZA), 6-mercaptopurine (6MP)) need additional treatment with infliximab (IFX). It remains unclear when IFX treatment can be stopped. Subgroup analyses of trials on the effectiveness of IFX have shown better effectiveness for reaching the endpoint of remission for the combination therapy. Therefore, patients are treated with the IFX/IS combination for extended periods. Recently an alarming rise in incidence of hepatosplenic T cell lymphomas in younger CD patients on IFX/IS therapy has been noted. Concerns about the neoplastic complications of IFX in combination with IS have highlighted the need to taper medication at some point in the treatment. Obviously medication should only be tapered when remission of disease is reached. It remains unclear whether either IFX or IS should be stopped. Unpublished results from a trial by the Leuven group show that continuing therapy with IFX alone in patients that are in remission for 6 months, is equally effective when compared with continuing IFX/IS combination therapy. However, this study did not contain a treatment arm in which the IFX was stopped and patients were maintained on IS alone. The effectiveness of AZA, the IS agent tested by the Leuven group, in maintaining remission of disease is well established and reputed by European guidelines.

The aim of this study is to compare the effectiveness of IS (AZA or 6MP) mono therapy with IFX mono therapy in CD patients with quiescent disease, defined by a Crohn's Disease Activity Index (CDAI) below 150.

The study is designed as a multicenter, randomized non-inferiority clinical trial (PROBE design) including CD patients with disease located in colon or the terminal ileum that have been in remission while on IFX/IS combination therapy for at least 6 months. After assessing mucosal healing by means of a colonoscopy patients will be randomized into two treatment arms:

continuing on IFX mono therapy or continuing on the IS agent the patient already used before randomization (AZA or 6MP).

Outcomes are: number of relapses (primary outcome), mucosal healing, number of treatment failures, time to relapse and quality of life. To show non-inferiority between IFX mono treatment and IS mono treatment 64 patients per treatment arm are needed.

## **Doel van het onderzoek**

Immuune suppression therapy (azathioprine or 6-Mercaptopurine) maintenance therapy is as effective as infliximab maintenance therapy after remission induction with combined infliximab/immune suppression therapy for at least 6 months.

## **Onderzoeksopzet**

- Patients will receive therapy at intervals of 6 to 12 weeks.
- 12 months follow-up

## **Onderzoeksproduct en/of interventie**

- Infliximab:

Patients randomly allocated to continuing on IFX mono therapy will continue maintenance treatment with IFX. Comedication by means of AZA or its derivate 6MP will be stopped. Maintenance treatment will consist of infusions of 5 mg/kg. Patients will receive maintenance therapy at intervals of 6 to 12 weeks.

- Azathioprine:

Patients randomly allocated to continuing on IS (AZA/6MP) mono therapy will discontinue treatment with IFX; only AZA or 6MP will be continued. If patients received IFX in combination with AZA before randomization they will only continue AZA; if patients received IFX in combination with 6MP they will continue using 6MP. Dosages will be the same as before randomization.

For AZA this will be a dose of 2.5 mg/kg daily; 6MP will be continued in a dose of 1,5 mg/kg daily.

## **Contactpersonen**

### **Publiek**

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## **Wetenschappelijk**

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## **Deelname eisen**

### **Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)**

1. Age between 18 and 80
2. For at least 6 months a stable dose of combination therapy with IFX and AZA or with IFX and 6MP
3. CD in remission for at least 6 months

### **Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)**

1. Failed attempt to quit medication during combination therapy before
2. Abdominal abscesses, fistulas and fluid collections
3. Comorbidity or extra-intestinal complications that require infliximab treatment
4. Crohn's disease activity of the upper gastrointestinal tract that requires infliximab treatment
5. Legally incompetent patients

# Onderzoeksopzet

## Opzet

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

## Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	01-08-2008
Aantal proefpersonen:	130
Type:	Verwachte startdatum

## Ethische beoordeling

Positief advies	
Datum:	13-08-2008
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	NL1344
NTR-old	NTR1404
Ander register	AMC-MEC projectcode : 08/101
ISRCTN	ISRCTN wordt niet meer aangevraagd

## Resultaten

### Samenvatting resultaten

N/A