

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

No registrations found.

<b>Ethical review</b>	Positive opinion
<b>Status</b>	Recruiting
<b>Health condition type</b>	-
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON21255

### Source

NTR

### Brief title

Azorix trial

### Health condition

Crohn's disease in remission

## Sponsors and support

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

**Source(s) of monetary or material Support:** No funding source

## Intervention

## Outcome measures

### Primary outcome

The occurrence of relapse - defined as a disease activity with a CDAI score greater than 150 -

during the 12 months follow-up period.

### **Secondary outcome**

1. Mucosal healing at 12 months
2. Number of treatment failures after 12
3. Time to relapse
4. HRQOL at 12 months, measured by IBDQ

## **Study description**

### **Background summary**

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 Unpublished results from a trial by the Leuven group show that continuing therapy with IFX alone in patients that are in remission for 6 months, is equally effective when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.

## **Study objective**

Immune 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.

## **Study design**

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

## **Intervention**

- Infliximab:

Patients randomly allocated to continuing on IFX mono therapy will continue maintenance treatment with IFX. Comedication by means of AZA or its derivative 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.

## **Contacts**

### **Public**

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## Eligibility criteria

### Inclusion criteria

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

### Exclusion criteria

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

## Study design

### Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

### Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	01-08-2008
Enrollment:	130
Type:	Anticipated

## Ethics review

Positive opinion	
Date:	13-08-2008
Application type:	First submission

## 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	NL1344
NTR-old	NTR1404
Other	AMC-MEC projectcode : 08/101
ISRCTN	ISRCTN wordt niet meer aangevraagd

## Study results

### Summary results

N/A