# Azathioprine maintenance treatment versus Infliximab maintenance treatment in Crohn's disease patients in remission

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This study aims to show that the IFX or AZA are equally effective with the latter being more efficient as maintenance therapy in CD after remission induction with IFX/AZA for at least 6 months as defined by the proportion of patients not needing…

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| **Ethical review** | Approved WMO |
| **Status** | Pending |
| **Health condition type** | Gastrointestinal inflammatory conditions |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON32054

**Source**
ToetsingOnline

**Brief title**
Azorix trial

### Condition

- Gastrointestinal inflammatory conditions
- Autoimmune disorders

**Synonym**
chronic inflammatory bowel disease, Crohn's disease

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Academisch Medisch Centrum
**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** Azathioprine, Crohn's disease, Infliximab, Remission

## 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. Presence of mucosal healing at 12 months

2. Number of treatment failures during the 12 months follow-up period

3. Time to relapse

4. The patients' level of health related quality of life (HROQL) at the end of

the study period, assessed by the IBDQ questionnaire

# Study description

### Background summary

Crohn disease (CD) patients that have a flare of disease activity while on immune suppressive (IS) medication (azathioprine (AZA), 6-mercaptopurine (6MP) and methotrexaat) need additional treatment with infliximab (IFX). It remains unclear when IFX treatment can be stopped. Subgroup analyses of the initial 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 costs of IFX monotherapy by far exceed the costs of IS monotherapy.
The aim of this study is to compare the effectiveness of IS (AZA or 6MP) monotherapy with IFX monotherapy 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 clinical trial 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 stratified for mucosal healing and randomized in to two treatment arms: continuing on IFX monotherapy 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, and quality of life. To show non-inferiority between IFX mono treatment and IS mono treatment 64 patients per treatment arm are needed.
Patients will be recruited from June 2008 until June 2009 with a minimal follow-up period of 1 year.

### Study objective

This study aims to show that the IFX or AZA are equally effective with the latter being more efficient as maintenance therapy in CD after remission induction with IFX/AZA for at least 6 months as defined by the proportion of patients not needing more intense treatment due to relapse of disease.

### Study design

Probe: Prospective, Randomised, Open treatment, Blind End-point evaluation

### Intervention

na

### Study burden and risks

The burden and risks associated with the treatments are subject of this study. Participation does not impose other risks and the burden will be limited to a minor time investment by the patient

## Contacts

### Public

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# Trial sites

## Listed location countries

Netherlands

# Eligibility criteria

**Age**
Adults (18-64 years)
Elderly (65 years and older)

## Inclusion criteria

- age > 18
- At least 6 months a stable dose of combination therapy with IFX and AZA or with AZA and 6MP
- Crohn's Disease in remission (defined by a CDAI lower than 150 points) for at least 6 months

## Exclusion criteria

- Abdominal abscesses, fistulas and fluid collections
- Co morbidity or extra-intestinal complications that require infliximab treatment
- Crohn's disease activity of the upper gastrointestinal tract that requires infliximab treatment
- Age > 80 years
- Legally incompetent patients

# Study design

## Design

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|---|---|
| Study type: | Interventional |
| Intervention model: | Parallel |
| Masking: | Open (masking not used) |
| Control: | Uncontrolled |
| Primary purpose: | Treatment |

## Recruitment

NL

| | |
|---|---|
| Recruitment status: | Pending |
| Start date (anticipated): | 01-06-2008 |
| Enrollment: | 128 |
| Type: | Anticipated |

## Medical products/devices used

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|---|---|
| Product type: | Medicine |
| Brand name: | Immuran |
| Generic name: | Azathioprine |
| Registration: | Yes - NL intended use |
| Product type: | Medicine |
| Brand name: | Remicade |
| Generic name: | Infliximab |
| Registration: | Yes - NL intended use |

# Ethics review

Approved WMO

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| Date: | 04-04-2008 |
| Application type: | First submission |
| Review commission: | METC Amsterdam UMC |

Approved WMO

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|---|---|
| Date: | 20-07-2009 |
| Application type: | Amendment |
| Review commission: | METC Amsterdam UMC |

# 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 |
|---|---|
| EudraCT | EUCTR2008-001131-35-NL |
| CCMO | NL22219.018.08 |