# The effect of TNFα-blockers on B-cells in patients with granulomatous diseases.

Published: 13-03-2014
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Primary Objective: To identify new immunological markers for therapeutic response to anti-TNF therapy in chronic granulomatous diseases.

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| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Gastrointestinal inflammatory conditions |
| **Study type** | Observational invasive |

## Summary

### ID

NL-OMON41509

**Source**
ToetsingOnline

**Brief title**
TNFα-blockers and B-cells in granulomatous diseases.

### Condition

- Gastrointestinal inflammatory conditions
- Autoimmune disorders

**Synonym**
Inflammatory systemic diseases

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Erasmus MC, Universitair Medisch Centrum Rotterdam
**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** B-cells, Biologicals, Granulomatous

## Outcome measures

### Primary outcome

To assess the B-cell maturation in patients with granulomatous diseases.

### Secondary outcome

Not applicable.

# Study description

### Background summary

Sarcoidosis and Crohn*s disease are different entities, but are both characterized by formation of granulomas by a T-cell mediated immune response. Treatment is often similar, in particular regarding the use of biologicals as TNFα-blockers. Recent studies indicate maturation disturbances in B-cell in both in sarcoidosis and Crohn*s disease. However, B-cell maturation patterns differ between the two diseases, which might indicate a different immunopathogenesis. TNFα-blockers are increasingly implemented in the treatment of both diseases, but are expensive, can cause side effects and are not always successful. It would be valuable to use B-cells as a (predictive) marker for therapeutic response. We have previously demonstrated that changes in the numbers of the CD27-IgA+ B-cell subset in blood might indicate therapeutic response to TNF-blockers in sarcoidosis. We here aim to monitor the blood B-cell compartment before and during TNF-blockers in patient groups suffering from two different types of granulomatous disease to increase our understanding of the immune system and identify biomarkers to predict response to biologicals.

### Study objective

Primary Objective: To identify new immunological markers for therapeutic response to anti-TNF therapy in chronic granulomatous diseases.

### Study design

To study the effect of biological therapy on B-cell maturation, patients with granulomatous disease such as sarcoidosis and Crohn*s disease who are indicated

for biological therapy, will be included. Patients are not to be prescribed biologicals specifically for this study. Blood withdrawal will take place in patients before start and during therapy with TNFα-blockers. To obtain insight in the pharmacodynamic processes of these agents, B-cell maturation will be studied four times per patient with a follow up of eight months from start of therapy.

### Study burden and risks

There are no benefits as it is an observational study. However, the only burden to this study is extra blood withdrawal when venous punction is already scheduled, either for regular check-ups, or for therapy with infliximab.

## Contacts

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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 years
Biopsy proven sytemic granulomatous disease as Crohn's Disease/Sarcoidosis
Intention to start treatment with TNFα-blockers; infliximab

### Exclusion criteria

Age < 18

## Study design

### Design

**Study type:** Observational invasive

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|---|---|
| Masking: | Open (masking not used) |
| Control: | Uncontrolled |
| Primary purpose: | Basic science |

### Recruitment

NL

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|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 03-04-2014 |
| Enrollment: | 40 |
| Type: | Actual |

## Ethics review

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| Approved WMO Date: | 13-03-2014 |
| Application type: | First submission |
| Review commission: | METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam) |
| Approved WMO Date: | 31-07-2015 |

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| Application type: | Amendment |
| Review commission: | METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam) |

# 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 |
|---|---|
| CCMO | NL47256.078.13 |