

# Study on genetic factors in the pathogenesis of Inflammatory Bowel Disease: Gathering a matched control population

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The objective of the study is to gather as many DNA samples of partners of IBD patients and parents of adult IBD patients as possible. By assessing allele and genotype frequencies in IBD patients and the control cohort, novel genetic risk factors...

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Pending
<b>Health condition type</b>	Gastrointestinal inflammatory conditions
<b>Study type</b>	Observational invasive

## Summary

### ID

NL-OMON30241

### Source

ToetsingOnline

### Brief title

AENEAS

### Condition

- Gastrointestinal inflammatory conditions
- Autoimmune disorders

### Synonym

Crohn's disease, Ulcerative Colitis

### Research involving

Human

## Sponsors and support

**Primary sponsor:** Academisch Medisch Centrum

**Source(s) of monetary or material Support:** Winstreserve AMR

## Intervention

**Keyword:** controls, genes, IBD, polymorphisms

## Outcome measures

### Primary outcome

Allele frequencies of candidate genes.

### Secondary outcome

Genotype frequencies

## Study description

### Background summary

The pathogenesis of inflammatory bowel disease (IBD) remains unclarified. However, it has become clear that luminal antigens trigger a chronic inflammatory reaction in a genetically susceptible host. For one of the two currently distinguished clinical phenotypes of IBD, Crohn\*s disease (CD), genetic risk factor have been identified. These polymorphisms are only found is a minority of the patients. Therefore our group has collected a IBD-DNA bank over the last years. To compare allele and genotype frequencies that our found in this DNA-bank we are in need of a well-matched control-DNA cohort. Partners of IBD patient could form such a controle group since they are exposed to the same environmental factors, most often share the same social-economic background and most often are members of the same ethnic group. An alternative test for disease association can be done by transmission disequilibrium testing (TDT) for which DNA of parents of IBD patient is needed.

### Study objective

The objective of the study is to gather as many DNA samples of partners of IBD patients and parents of adult IBD patients as possible. By assessing allele and genotype frequencies in IBD patients and the control cohort, novel genetic risk factors may be identified. These association can be confirmed by transmission disequilibrium testing. Identification of genetic risk factors provide new

insights in the pathogenesis of IBD.

### **Study design**

Parents and partners of adult IBD patients will be asked to donate blood for DNA isolation following informed consent. Blood donation will consist of 14 ml EDTA blood. DNA extraction out of white blood cells will be performed by standard DNA extraction techniques. DNA samples will be stored anonymously at 4 degrees celsius

### **Study burden and risks**

Negligible

## **Contacts**

### **Public**

Academisch Medisch Centrum

Meibergdreef 9  
1105 AZ Amsterdam  
NL

### **Scientific**

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## **Trial sites**

### **Listed location countries**

Netherlands

## **Eligibility criteria**

### **Age**

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

## Inclusion criteria

Subject should be partner of an adult IBD patient, or a parent of an adult IBD patient

## Exclusion criteria

Not fulfilling inclusion criteria

## Study design

### Design

**Study type:** Observational invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Basic science

### Recruitment

NL

Recruitment status: Pending

Start date (anticipated): 12-10-2006

Enrollment: 3000

Type: Anticipated

## Ethics review

Approved WMO

Application type: First submission

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**

<b>Register</b>	<b>ID</b>
CCMO	NL14649.018.06