

# Gastrointestinal pathology in patients with hypogammaglobulinaemia.

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**Primary Objective** The prevalence and incidence of (pre)malignant and inflammatory pathology in the gastrointestinal tract of patients with a primary antibody deficiency (CVID, XLA, IgG subclass deficiency and abnormal vaccination responses). **Secondary...**

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Immunodeficiency syndromes
<b>Study type</b>	Observational invasive

## Summary

### ID

NL-OMON33548

### Source

ToetsingOnline

### Brief title

Gastrointestinal pathology in patients with hypogammaglobulinaemia.

### Condition

- Immunodeficiency syndromes

### Synonym

primary immunodeficiency

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Universitair Medisch Centrum Utrecht

**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** Gastrointestinal, hypogammaglobulinaemia, pathology

## Outcome measures

### Primary outcome

The prevalence and incidence of (pre)malignant and inflammatory pathology in the gastrointestinal tract of patients with a primary antibody deficiency (CVID, XLA, IgG subclass deficiency and abnormal vaccination responses).

### Secondary outcome

(1) Prevalence of asymptomatic carrier of bacterial, viral and/or parasitic pathogens.

(2) Identification of subgroups within the group of CVID patients: determination of possible relationship with (B cell) phenotype and genotype (CVID related B cell mutations) and the gastrointestinal pathology.

## Study description

### Background summary

An important focus of interest at the outpatient clinic of infectious diseases of the university hospital of infectious diseases are patients with a primary immunodeficiency.

The group of patients with a primary antibody deficiency (CVID, XLA, IgG subclass deficiency and abnormal vaccination responses) form a large portion of this group of patients. Currently there are 73 patients and per year 10 new patients.

The focus of this research project will be the gastrointestinal pathology in the gastrointestinal tract of patients with a primary antibody deficiency (CVID, XLA, IgG subclass deficiency and abnormal vaccination responses).

### Study objective

### Primary Objective

The prevalence and incidence of (pre)malignant and inflammatory pathology in the gastrointestinal tract of patients with a primary antibody deficiency (CVID, XLA, IgG subclass deficiency and abnormal vaccination responses).

### Secondary Objective(s):

(1) Prevalence of asymptomatic carrier of bacterial, viral and/or parasitary pathogens.

(2) Identification of subgroups within the group of CVID patients: determination of possible relationship with (B cell) phenotype and genotype (CVID related B cell mutations) and the gastrointestinal pathology.

### Study design

Cross sectional analysis during a regularly performed gastroscopy and colonoscopy with extra biopsies of colon tissue.

Prospective follow study after 3 years

### Study burden and risks

Colonoscopy and gastroscopy are part of the regular 3 year follow up of patients with a primary antibody deficiency.

The risks related to this research project are related to the extra colon biopsies. The risk of perforation or bleeding is 1:5000 biopsies.

## Contacts

### Public

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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

Primary antibody deficiency:

1. Common Variable Immunodeficiency Syndrome (CVID)
2. X-linked agammaglobulinemia (XLA)
3. IgG subclass deficiency
4. abnormal vaccination response

### Exclusion criteria

incapable to sign informed consent

Age younger than 18 years.

## Study design

### Design

**Study type:** Observational invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Basic science

### Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 08-08-2009

Enrollment: 70

Type:

Actual

## Ethics review

Approved WMO

Date:

14-07-2009

Application type:

First submission

Review commission:

METC Universitair Medisch Centrum Utrecht (Utrecht)

## 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**

CCMO

**ID**

NL25742.041.08