

# Coeliac disease in infertile Dutch couples

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1.To study the prevalence of diagnosed and undiagnosed/untreated coeliac disease in male-female couples visiting an infertility clinic.2. To study the relevance of routine antibody screening for coeliac disease in all patients with infertility...

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

## Summary

### ID

NL-OMON31689

### Source

ToetsingOnline

### Brief title

Coeliac disease and infertility

### Condition

- Gastrointestinal inflammatory conditions
- Pregnancy, labour, delivery and postpartum conditions

### Synonym

Coeliac disease, coeliac sprue, glutenenteropathy

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Leids Universitair Medisch Centrum

**Source(s) of monetary or material Support:** Farmaceutische industrie: Pharmacia  
,Pharmacia

## Intervention

**Keyword:** Artificial Reproduction Techniques (ART), Coeliac disease, Infertility

## Outcome measures

### Primary outcome

Number of infertile females and males in whom coeliac disease is diagnosed in this study.

### Secondary outcome

Gender, age, ethnicity, body mass index and diagnostic category for infertility.

## Study description

### Background summary

Untreated coeliac disease is found in 4-8% of infertile women visiting infertility clinics. In male untreated coeliac patients, infertility has been described in smaller case-series. The pathophysiological mechanism of infertility in coeliac disease patients is multifactorial and incompletely understood. Treatment of coeliac disease with a gluten-free diet has been described that it could restore fertility in both sexes.

Hypothesis: Assisted reproduction techniques may be prevented in a substantial number of couples visiting a Dutch infertility clinic through active detection and treatment of coeliac disease.

### Study objective

1. To study the prevalence of diagnosed and undiagnosed/untreated coeliac disease in male-female couples visiting an infertility clinic.
2. To study the relevance of routine antibody screening for coeliac disease in all patients with infertility visiting an infertility clinic.

### Study design

For females, screening for celiac disease has been implemented as part of the standard diagnostic work-up in the participating infertility clinics. For males, informed consent will be required to be included in the study.

Detection of CD will be performed through

1. Detection of IgA TTG antibodies in serum as part of the standard diagnostic work-up for infertility in the infertility clinics of the LUMC and Medical Centre Haaglanden, Westeinde.
2. In case of a positive serological test, the diagnosis for coeliac disease will be confirmed by endoscopic small bowel biopsy, after informed consent. CD is diagnosed if internationally accepted histological criteria for CD are presented. All CD patients will be invited to start with a GFD.

Odds ratios for coeliac disease will be calculated for gender, age, ethnicity, body mass index and diagnostic category for infertility.

### **Study burden and risks**

No extra risks will be involved by obtaining 5ml of extra blood. And no extra venous blood puncture has to be performed for this study because the blood withdrawal will be implemented as part of the standard diagnostic work-up of the infertility clinics.

In case of a positive serological test, the diagnosis for coeliac disease will be confirmed by endoscopic small bowel biopsy after informed consent.

## **Contacts**

### **Public**

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### **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

All consecutive male-female couples attending the infertility clinic for the first time.

### Exclusion criteria

Couples that require donor insemination are excluded, because screening for celiac disease will not be possible in the donor.

## Study design

### Design

**Study type:** Observational invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Diagnostic

### Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 01-04-2008

Enrollment: 2840

Type: Anticipated

## Ethics review

Approved WMO

Application type:

First submission

Review commission:

METC Leids Universitair Medisch Centrum (Leiden)

## 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	NL20939.058.08