Coeliac disease in infertile Dutch couples

Published: 18-08-2008
Last updated: 07-05-2024

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...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Gastrointestinal inflammatory conditions
Study type	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: Artifical 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 infertily 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

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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