The significance of intraepithelial lymfocytosis without villous atrophy for the diagnosis of celiac disease.

Published: 27-11-2008
Last updated: 05-05-2024

To study the prevalence of HLA DQ2 or DQ8 gene locus and celiac disease in patients in which previously idiopathic intraepithelial lymfocytosis without villous atrophy was found.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Malabsorption conditions
Study type	Observational invasive

Summary

ID

NL-OMON32813

Source
ToetsingOnline

Brief title
Marsh 1 study

Condition

- Malabsorption conditions
- Food intolerance syndromes

Synonym
celiac disease, sprue

Research involving
Human

Sponsors and support

Primary sponsor: Isala Klinieken
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: celiac disease, HLA DQ2 or DQ8, intraepithelial lymfocytosis, Marsh 1

Outcome measures

Primary outcome

Primary outcome is the prevalence of HLA DQ2 or DQ8.

Secondary outcome

Secundary outcome is the prevalence of anti-endomysium antibodies and

anti-tissue transglutaminase antibodies. Quality of life.

Study description

Background summary

Celiac disease is a small bowel disorder that occurs upon exposure to gluten and is characterized by abdominal symptoms and malabsorption and long term complications like infertility, osteoporosis and small bowel malignancies. There is a strong association between celiac disease and HLA DQ2 and/or DQ8. The absence of HLA DQ2 or DQ8 virtually excludes celiac disase. The histological abnormalities associated with celiac disease are classified according to Marsh. Marsh 1 denotes an increased number of intraepithelial lymfocytes without villous atrophy. Intraepitehial lymfocytosis without villous atrophy is also observed in other small bowel disorders. As the absence of HLA DQ2 or DQ8 excludes celiac disease in patients with Marsh 1 in duodenal biopsy specimens we hypothesized that the prevalence of HLA DQ2 or DQ8 is significantly higher in pateints with intraepithelial lymfocytosis only as compared to the general population if this condition is associated with celiac disease.

Study objective

To study the prevalence of HLA DQ2 or DQ8 gene locus and celiac disease in patients in which previously idiopathic intraepithelial lymfocytosis without villous atrophy was found.

Study design

Patients with intraepithelial lymfocytosis without villous atrophy will be

included. Patients will be asked about abdominal symptoms or signs consistent with celiac disease. Patient will also be checked for symptoms suggestive of irritable bowel syndrome according to the Rome III criteria. Additinally, patients will be asked to fill out a quality of life questionnaire (RAND-36). Finally, in all included patients 10 ml of blood will be drawn to analyse HLA DQ2 or DQ8, anti-endomysium antibodies and anti-tissue transglutaminase antibodies.

Study burden and risks

A minimal burden consisting of filling out questionnaires and drawing 10 ml of blood once.

Contacts

Public
Isala Klinieken

Postbus 10400
8000 GK Zwolle
Nederland
Scientific
Isala Klinieken

Postbus 10400
8000 GK Zwolle
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

1. Idiopathic intraepithelial lymfocytosis without villus atrophy (Marsh 1)
2. Accountable
3. Above 18 years of age
4. Written informed consent

Exclusion criteria

1. Proven celiac disease, Crohn's disease, infection with Helicobacter pylori or Giardia lamblia, small bowel vascular disease
2. Non-accountable
3. Under 18 years of age
4. No written informed consent

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):	01-12-2008
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO

Date:	27-11-2008
Application type:	First submission

Review commission: METC Isala Klinieken (Zwolle)

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	NL25270.075.08