Screening first-degree relatives of Celiac Disease patients, does it affect gastro-intestinal symptoms and quality of life?

Published: 01-09-2009
Last updated: 06-05-2024

The aim of this randomized controlled trial is to determine the affect of screening on the Gastrointestinal symptoms (GIS) and Health Related Quality of Life (HRQL) in asymptomatic first degree relatives of CD patients. On the basis of the results,...

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

Summary

ID

NL-OMON36924

Source
ToetsingOnline

Brief title
Screening first-degree relatives of Celiac Disease patients

Condition

- Malabsorption conditions
- Autoimmune disorders

Synonym
celiac sprue, gluten intolerance

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Ministerie van OC&W,WKZ fonds

Intervention

Keyword: Celiac Disease, Quality of life, Screening

Outcome measures

Primary outcome

The primary parameters of this study will be the HRQL and GIS scores before and after screening.

Secondary outcome

The secondary parameter will be the total days of absence from school or work before and after screening.

Study description

Background summary

Celiac Disease (CD) is an affliction which occurs in genetically susceptible individuals upon the ingestion of gluten. The prevalence of CD in the general population is estimated to be 0.5-1%, but approaches 16% in first degree relatives. Given this increased prevalence rate every time an index patient is diagnosed, first degree relatives will often be screened for CD.
In symptomatic individuals, approximately half of the first degree relatives, a gluten free diet significantly improves gastrointestinal symptoms and the quality of life. Therefore, screening is justified in symptomatic relatives. By contrast, in asymptomatic individuals it is unknown whether they will benefit from a gluten free diet, either physically or psychosocially. Despite this, symptom free relatives of an index patient with CD are often being screened for CD

Study objective

The aim of this randomized controlled trial is to determine the affect of screening on the Gastrointestinal symptoms (GIS) and Health Related Quality of Life (HRQL) in asymptomatic first degree relatives of CD patients. On the basis of the results, it would be possible to conclude whether screening is justified in this group.

Study design

Subjects will be included over a period of 2 years. Directly after informed consent, all subjects will receive two sets of questionnaires, validated to measure HRQL, using the SF-36, and GIS, using the Gastro-intestinal Symptoms Questionnaire. Subsequently, all symptomatic relatives will be screened for CD. Asymptomatic relatives will be randomized to either immediate screening, or the option to have these investigations done later on. Six months after screening or randomization, the questionnaires will be distributed again.
Along with the questionnaires, the participants will be asked to report the total days of absence from work or school.

Screening is done in a two step approach: firstly by determining HLA-DQ2/DQ8, and if any of these HLA class I molecules are present, the determination of IgA-antiendomysium antibodies (EMA), and IgA-tissuetransglutaminase antibodies (TTG), as well as total IgA. Those relatives with abnormal results for either EMA or TTG will be offered a small intestinal biopsy to prove the existence of CD. This is the standard diagnostic approach in symptomatic and asymptomatic persons. Subjects in whom celiac disease is confirmed, will start a gluten free diet.

Study burden and risks

Because the diagnostic approach to screen for CD will not be different from the approach maintained in clinical practice, no increased risk to the participants is expected. The burden associated with participation in this study is thought to be minimal as filling out the questionnaires is expected to take only 30 minutes

Contacts

Public
Universitair Medisch Centrum Utrecht

Lundlaan 6
3584 CX, Utrecht
NL
Scientific
Universitair Medisch Centrum Utrecht

Lundlaan 6
3584 CX, Utrecht
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Children (2-11 years)
Elderly (65 years and older)

Inclusion criteria

First degree relatives older than 2 years.

Exclusion criteria

Celiac disease already diagnosed
Screened before
Already on a gluten free diet

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	02-11-2009
Enrollment:	240
Type:	Actual

Ethics review

Approved WMO Date:	01-09-2009
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	18-01-2012
Application type:	Amendment
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	ID
CCMO	NL25604.041.08