Celiac disease: interplay between genes and the environment. Towards the unraveling of disease initiating events.

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Ethical review	Approved WMO
Status	Pending
Health condition type	Metabolic and nutritional disorders congenital
Study type	Observational invasive

Summary

ID

NL-OMON29784

Source
ToetsingOnline

Brief title
Celiac disease: interplay between genes and the environment.

Condition

- Metabolic and nutritional disorders congenital
- Malabsorption conditions
- Food intolerance syndromes

Synonym
coeliac disease, gluten intolerance, gluten-sensitive enteropathy

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum

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

Intervention

Keyword: celiac disease, children, genetics, immunology

Outcome measures

Primary outcome

Identification of (aberrant) molecular pathways leading to disease development.

Safer foods for coeliac patients

Gluten digesting drugs

Secondary outcome

Not applicable

Study description

Background summary

Dutch celiac disease researchers in the Leiden University Medical Center, the University Medical Center Utrecht, TNO Quality of Life and the Wageningen University have joined forces in a research project called the Celiac Disease Consortium (CDC). The CDC is co-ordinated by the LUMC and funded by the Dutch government.

As celiac disease is a disease that is exclusively found in humans, this research depends on the ongoing availability of patient derived materials. Such material can be obtained through routine diagnostic procedures, like venous blood sampling and the sampling of intestinal biopsies during diagnostic endoscopy.

Through this protocol we ask for continued permission to obtain 10 ml extra of venous blood and 4 extra duodenal biopsies, through asking informed consent to sample extra patient material in all consecutive children that undergo upper gastrointestinal endoscopy as a part of their individual diagnostic workup in

the LUMC.

Study objective

The primary oblective of the study is to elucidate all molecular mechanisms leading to coeliac disease.

In order to establish the scientific basis for the development of improved diagnostics, novel therapies and safer foods for patients, in the CDC:

A Human Genomics research cluster will focus on the identification of (aberrant) molecular pathways leading to disease development.

A Food Genomics research cluster will concentrate on reduction of gluten intake.

Study design

In the CDC, the patient derived materials will be used within the framework of teh Human Genomics Cluster to perform:

Functional studies of T-cell lines isolated from intestinl biopsies

Changes in protein expression patterns derived from intesitinal biopsies

Genetic studies in DNA isolated from blood lymphocytes and in mRNA isolated from intestinal biopsies.

Study burden and risks

From each patient, 4 extra duodenal biopsies and 10 ml of venous blood will be obtained. It is emphasized that in all cases the children undergo endoscopy as a workup for upper gastro-intestinal disease and not for the purpose of scientifc research. Since the endoscopy in children is routinely performed under general anesthesia, for which intravenous catheterization is mandatory, blood samples and biopsies can be drawn during anesthesia without extra burden or risk to the patients.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)

Inclusion criteria

1. All children that undergo upper gastrointestinal endoscopy in the Willem-Alexander Kinder- en Jeugd Centrum of the Leiden University Medical Center are eligible for the study.;2. Informed consent.

Exclusion criteria

1. Increased risk for bleeding or perforation.
2. No informed consent.

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2006
Enrollment:	600
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL13313.058.06