Prospective Celiac Disease Diagnosis Evaluation (ProCeDE).

Published: 21-01-2013
Last updated: 30-04-2024

Aim: To investigate the performance of the new ESPGHAN diagnostic criteria for celiac disease in practice in different European countries.Primary aim: To evaluate whether the omission of biopsies in selected pediatric cases does result in certain...

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

Summary

ID

NL-OMON37411

Source
ToetsingOnline

Brief title
ProCeDE

Condition

- Malabsorption conditions

Synonym
coeliac disease, sprue

Research involving
Human

Sponsors and support

Primary sponsor: European Society of Peadiatric Gastroenterology, Hepatology and Nutrition
Source(s) of monetary or material Support: ESPGHAN;Deutsche Zöliakie Gesellschaft;Danish Celiac Disease Association;Phadia-Thermofisher. Andere farmacie en coeliakieverenigingen uit diverse Europese landen zijn aangeschreven voor subsidie.,Phadia-

Thermofisher

Intervention

Keyword: celiac disease, diagnosis, evaluation guidelines, prospective study

Outcome measures

Primary outcome

To evaluate whether the omission of biopsies in selected pediatric cases does result in certain diagnosis of celiac disease (avoid false positive diagnosis of celiac disease).

Secondary outcome

- To evaluate characteristics and severity of symptoms in relation to histology and celiac disease specific antibody titers.

- To determine the best optimal cut-off point for antibody levels in children with symptoms of celiac disease which predict mucosal damge with 99% specificity.

- To determine whether the determination of HLA typing adds diagnostic value in cases with positive specific antibodies.

- To determine which of the available antibody tests (TG2, EMA, DGP) are most suitable for the initial diagnosis in relation to age and type of symptoms.

Study description

Background summary

Celiac disease is a frequently diagnosed chronic disease of the small bowel. Gluten causes mucosal damage of the small intestine. Gluten is present in the following grains: wheat, barley, and rye and almost any foods made therefrom. Undiagnosed and/or untreated celiac disease gives a severity of clinical

symptoms. Celiac disease is treated by a gluten free diet (GFD). A GFD is not easy to follow and it can affect quality of life (QoL). Small bowel biopsies have so far been considered as the reference standard for the diagnosis of celiac disease. However, during the last decades evidence has accumulated on the diagnostic value of specific celiac disease antibodies, and HLA typing has increasingly been used for diagnostic purposes. At the same time, the leading role of histology for the diagnosis of CD has been questioned.
Therefore new diagnostic guidelines/criteria for CD were developed by the ESPGHAN working group. This current study investigates the performance of the new ESPGHAN diagnostic criteria for celiac disease in practice in different European countries and especially evaluates whether the omission of biopsies in selected pediatric cases does result in certain diagnosis of celiac disease (avoid false positive diagnosis of celiac disease).

Study objective

Aim: To investigate the performance of the new ESPGHAN diagnostic criteria for celiac disease in practice in different European countries.

Primary aim: To evaluate whether the omission of biopsies in selected pediatric cases does result in certain diagnosis of celiac disease (avoid false positive diagnosis of celiac disease).

Secondary aims:
- To evaluate characteristics and severity of symptoms in relation to histology and celiac disease specific antibody titers.
- To determine the best optimal cut-off point for antibody levels in children with symptoms of celiac disease which predict mucosal damge with 99% specificity.
- To determine whether the determination of HLA typing adds diagnostic value in cases with positive specific antibodies.
- To determine which of the available antibody tests (TG2, EMA, DGP) are most suitable for the initial diagnosis in relation to age and type of symptoms.

Study design

Prospective multicenter observation study in 600 children with suspected celiac disease who will be diagnosed based on serology and duodenal biopsies plus in addition more extensive serology, HLA testing, and standardized symptom assessment. The children wiil be followed for 18 months after diagnosis.

Study burden and risks

The study takes minimal extra time above the normal diagnostic procedure.

- During the follow up visits, besides the medical history, physical

examination and collection of blood, a standardized questionnaire will be filled on clinical symptoms and adherence to gluten free diet.

- Duodenal biopsies will be taken to diagnose celiac disease.

Risks for the participants:
- risk of anesthesia
- risk of endoscopy: bleeding

Both risks are very low, and so far small bowel biopsies have been considered as the reference standard for the diagnosis of celiac disease.
In our hospital, we didn't see any of the risks/complications described above.

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

Consecutive children (age > 6 months - < 18.0 years) with a high degree suspicion for celiac disease consuming a gluten containing diet:
- A child with clinical symptoms indicative of celiac disease plus a positive test of any titer specific height for celiac disease specific antibodies (TG2, EMA, DGP- cave positive DGP-titer alone does not quanlify the patient for biopsy!) or
- A child with an increased risk for celiac disease such as having relatives of celiac disease patients or patients with diseases associated with celiac disease (Hashimoto Thyroiditis, Type I DM, Down's symdrome) with no or mild unspecific clinical symptoms but with a positive test for celiac disease specific antibodies (positive test for TG2 and/or positive EMA (>1:10)).

Exclusion criteria

- Patient with symptoms that may indicate celiac disease, but negative celiac disease specific antibodies (TG2 or EMA), but normal IgA.
- Patient without symptoms, and negative celiac specific antibodies (TG2 and EMA)
- Malignancy
- Serious chronic infections such as HIV or tuberculosis or congenital immunodeficiency
- Contraindications for endoscopy/biopsies
- Parents did not sign consent form
- Parents can not read/are not able to understand to give informed consent

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-02-2013
Enrollment:	60

Type:	Actual

Ethics review

Approved WMO Date:	21-01-2013
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
Other	DRKS00003555
CCMO	NL40200.058.12