Biopsy in Adult CeD (Bio.A.CeD)- the ESsCD Consensus

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Prevalence of CeD is about 15 around the world with a variation from 1:100 to 1:300 in different geographical areas [2, 3]. The diagnosis is made out of case finding among at-risk population such as diarrhea, anemia, ibs-like abdominal complaints,...

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

Summary

ID

NL-OMON48090

Source
ToetsingOnline

Brief title
Biopsy in Adult CeD (Bio.A.CeD)- the ESsCD Consensus

Condition

- Malabsorption conditions
- Autoimmune disorders

Synonym
coeliac disease

Research involving
Human

Sponsors and support

Primary sponsor: Sint Antonius Ziekenhuis
Source(s) of monetary or material Support: geen financiering van toepassing

Intervention

Keyword: Adult, Bio.A.CeD, Biopsy, ESsCD

Outcome measures

Primary outcome

1) to know the predictive value of serology in the diagnosis of CeD in a

high-risk population (seropositive or high clinical suspicion)

2) to determine the serology cut-off best suited to predict the presence of

small bowel duodenal damage diagnostic for CD (Marsh > 2 and Marsh 3

separately)

Secondary outcome

not applicable

Study description

Background summary

Coeliac disease (CeD) is a multifactorial, autoimmune, multiorgan disease that occurs, upon the ingestion of gluten in genetically determined individuals.
The disease may present with a wide spectrum of symptoms and signs from the overt, severe malabsorption syndrome to the asymptomatic form [1].

Study objective

Prevalence of CeD is about 15 around the world with a variation from 1:100 to 1:300 in different geographical areas [2, 3]. The diagnosis is made out of case finding among at-risk population such as diarrhea, anemia, ibs-like abdominal complaints, fatigue, other autoimmune diseases such as thyroiditis, ibs or dyspepsia, relatives of a coeliac person with little or no symptoms at all, iron deficiency anemia, fatigue.
In the suspicion of CeD, the presence of highly specific serum antibodies supports the diagnosis. There are autoantibodies targeting the auto-antigen such as Antiendomysial (EMA) and anti-tissue transglutaminase (anti-tTG) antibodies and antibodies targeting the offending agent (gliadin) such as

antibodies against synthetic deamidated gliadin peptides (anti-DGPs)

Study design

prospective, multicentre, observational study

Study burden and risks

no extra risks

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

indication for biopsy in suspected celiac disease

Exclusion criteria

nvt

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):	20-11-2019
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO

Date:	29-07-2019
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL69084.100.19