Assessment of gluten intake of celiac patients on a gluten-free diet by chemical analysis of duplicate food portions

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Food intolerance syndromes
Study type	Observational non invasive

Summary

ID

NL-OMON45505

Source
ToetsingOnline

Brief title
C4C-study

Condition

- Food intolerance syndromes

Synonym
celiac disease, gluten intolerance

Research involving
Human

Sponsors and support

Primary sponsor: Wageningen Center for Food Sciences

Source(s) of monetary or material Support: NVWA

Intervention

Keyword: Celiac disease, Duplicate portions, Gluten

Outcome measures

Primary outcome

The endpoints of the study are 1) an overview of commonly used products in a GFD form the detailed food records and duplicate portions, 2) identification of products that are perceived to be gluten free but in reality still contain gluten, 3) determination of the amount of gluten present in these products and in the total diet, 4) an indicative overview of the average number and severity of GI complaints, and 5) analysis of the results for a scientific publication and report .

Secondary outcome

not applicable

Study description

Background summary

Diet therapy is the only treatment of celiac disease (CD). It requires life-long adherence to a gluten-free diet (GFD). The elimination of gluten from the diet usually leads to fast alleviation of clinical symptoms, although recovery of the intestinal mucosa can take months or even years. However, a GFD fails to alleviate symptoms in 7 to 30% of patients. Excluding all non-food related explanations, it is hypothesised that is due to unintended gluten exposure in the diet of celiac patients. The most accurate way to test this hypothesis is by analysing duplicate portions of the diet on gluten. As as first step we have tested this approach in a pilot study in nine patients. In this proposed study we expand the number of patients with 25 such to reach an observation study of good quality (due to more observations).

Study objective

The study has three main objectives: 1) To determine the exposure to gluten in celiac patients on a gluten free diet and the variance within this exposure, 2) to determine the gluten content of gluten free-labelled products commonly used by celiac patients on a GFD and 3) to explore whether the level of gluten intake is related to the number and severity of gastointestinal (GI) complaints

Study design

A cross-sectional observational study. Celiac patients present in the electronic patient database of the gastroenterology department of hospital De Gelderse Vallei, Ede, Canisius-Wilhelmina Ziekenhuis, Nijmegen and Rijnstate, Arnhem, will receive an invitation letter and information brochure. They will be pre-selected on basis of the in- and exclusion criteria mentioned below. At baseline participants receive a questionnaire to obtain information about general characteristics, their adherence to the GFD, perceived degree of gluten sensitivity and self-efficacy toward a GFD. Participants will keep a detailed food record and collect duplicate portions of all food products and mixed dishes consumed for two days.

Study burden and risks

Participants are asked to fill out a questionnaire about their general health, GI complaints, perceived gluten sensitivity and adherence to a GFD. In addition, participants are asked to keep a detailed food record and collect duplicate portions of all food products used for two days for which costst will be reimbursed. In total participants will receive 60 E for participation in the study. The study is non-invasive, however, keeping the food records and duplicate portion collection can be perceived as burdensome and time consuming. There are no risks associated with participation due to its observatory nature. Benefits for the individual participants are that they receive detailed information about the gluten content of their diet and that they contribute to advancement of knowlegde regarding their illness.

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

Age from 18 to 65 years at the time of recruitment
confirmed diagnosis of celiac disease through intestinal biopsy
adherence to a gluten-free diet for at least 1 year
anti-tTG measurements available in medical records (max 1 year old)

Exclusion criteria

having any co-morbidity; diabetes mellitus type 1, microscopic colitis, thyroid diseases
unable or unwilling to comply with the study procedures
wittingly consuming gluten
having exacerbation of GI complaints

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	26-06-2017
Enrollment:	25
Type:	Actual

Ethics review

Approved WMO

Date:	31-05-2017
Application type:	First submission
Review commission:	METC Wageningen Universiteit (Wageningen)

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	NL60157.081.16