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	Recruiting
Health condition type	Food intolerance syndromes
Study type	Observational non invasive

Summary

ID

NL-OMON42259

Source
ToetsingOnline

Brief title
C4C-study

Condition

- Food intolerance syndromes

Synonym
celiac disease, gluten intolerance

Research involving
Human

Sponsors and support

Primary sponsor: Wageningen Universiteit

Source(s) of monetary or material Support: Ministerie van economische zaken

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 gluten free diet from 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 overview of the average number and severity of GI complaints; 5. Feasibility of the study procedure in preparation of a larger study.

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 this 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 a first step we would like to test this approach in a pilot study.

Study objective

The pilot 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 gluten free diet and 3) To explore whether the level of gluten intake is related to the number and severity of gastrointestinal (GI) complaints.

Study design

A cross-sectional pilot study. Celiac patients will be made aware of the possibility to participate in the study by the gastroenterology department of hospital de Gelderse Vallei, Ede.
At baseline participants receive a questionnaire to obtain information about general characteristics, their adherence to the gluten free diet, perceived degree of gluten sensitivity and self-efficacy toward a gluten free diet. Participants will keep a detailed food record and collect duplicate portions of all food products and meals 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 gluten free diet. 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 costs will be reimbursed. In total participants will receive ¤60 for participation in the pilot 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 knowledge 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 25 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

Exclusion criteria

* Having any co-morbidity
*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:	Recruiting
Start date (anticipated):	06-08-2015
Enrollment:	10
Type:	Actual

Ethics review

Approved WMO

Date:	21-01-2015
Application type:	First submission
Review commission:	METC Wageningen Universiteit (Wageningen)

Not approved

Date:	28-04-2015
Application type:	Amendment
Review commission:	METC Wageningen Universiteit (Wageningen)

Not approved

Date:	08-06-2015
Application type:	Amendment
Review commission:	METC Wageningen Universiteit (Wageningen)

Not approved

Date:	18-11-2016
Application type:	Amendment
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	NL51472.081.14