Influence of Late Diagnosis on the Burden of disease in Adult Patients with Coeliac Disease.

Published: 18-06-2013
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The purpose of this study is to determine how diagnostic delay of CD affects the burden of CD to patients and society in terms of healthcare and mental healthcare utilisation and socioeconomic costs.

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

Summary

ID

NL-OMON40589

Source
ToetsingOnline

Brief title
Late diagnosis, disease burden and coeliac disease.

Condition

- Malabsorption conditions
- Autoimmune disorders

Synonym
Coeliac disease, gluten intolerance.

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Leiden
Source(s) of monetary or material Support: NWO;F. Koning;LUMC

Intervention

Keyword: Coeliac disease, Healthcare costs, Quality of Life

Outcome measures

Primary outcome

Quality Adjuste Life Years (QALY*s).

Secondary outcome

Secondary outcomes: Health care utilisation in Euros before and after

diagnosis, number and severity of medical symptoms and complications.

Predictors and mediators: Socioeconomic group.

Study description

Background summary

Despite the increased awareness of CD in society and in healthcare, there is still a substantial delay from first symptoms to diagnosis of CD. Undiagnosed patients with CD can be characterised as having poor HRQoL. HRQoL as an aspect of living with CD has been studied frequently. Untreated CD is associated with a variety of medical complications of which some are permanent or even fatal. Despite this there are still few studies who have examined the burden of disease in CD. The aim of the current study is to determine how diagnostic delay of CD affects the burden of CD to patients and society in terms of healthcare and mental healthcare utilisation and socioeconomic costs. In addition we will examine differences in outcome between patients belonging to different socioeconomic groups. We hope that this study will emphasize the fact that policy should be made to avoid unnecessary delay in diagnosis of CD. And that by shortening the diagnostic delay it may be possible to reduce the unnecessary burden of disease.

Study objective

The purpose of this study is to determine how diagnostic delay of CD affects the burden of CD to patients and society in terms of healthcare and mental healthcare utilisation and socioeconomic costs.

Study design

The study design will be a cross-sectional population study, designed to compare differences in quality of life and healthcare costs before and after diagnosis of CD in terms of Quality Adjusted Life Years (QALY*s).

Study burden and risks

No adverse effects of this study are expected. Questionnaire and interview completion involve an investment by the participant of approximately 1 hour and 45 minutes. The measures and the interview format used in this study are usually not experienced as stressful or burdensome.

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

Dutch citizen
Dutch-speaking
Age >=18
Confirmed diagnosis of CD based on medical expertise

Exclusion criteria

For questionnaire section of the study:
Participants who are not able to fill out the questionnaires themselves (for example due to cognitive conditions);For interview section of the study:
Serious physical, psychiatric or cognitive conditions that could threaten the validity of the interview or make the interview impossible (for example; deafness, mental retardation, psychosis).

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-05-2013
Enrollment:	3722
Type:	Anticipated

Ethics review

Approved WMO
Date: 18-06-2013

Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	22-04-2014
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

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	NL44374.058.13