Influence of the dietary history in the prevention of coeliac disease: possibilities of induction of tolerance for gluten in genetic predisposed children.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27354

Source
Nationaal Trial Register

Brief title
PREVENTCD

Health condition

coeliac disease (coeliakie); gluten; prevention (prevensie); breastfeeding (borstvoeding); early feeding (baby voeding); genetic predisposition (genetisch predispositie); HLA; food intervention (voedings interventie); prospective (prospectief); double blind; randomized (gerandomiseerd), multicenter; European (Europesse); EU FP6.

Sponsors and support

Primary sponsor: -
Source(s) of monetary or material Support: European Commission; contract NoFood-CT-2006-36383 project 'PREVENTCD'.
It's a Sixth Framework project.
In total is the financial support: 3.675.000,-
Divided over 2 studies; the family study and the population study.
The intervention family study has: 2.992.347,-euro
(and population study: 682.653,-euro)

Intervention

Outcome measures

Primary outcome

A reduction of 50% of CD among the intervention group at the age of 3 years will be considered as an effective prevention.

Secondary outcome

If the proposed early dietary intervention results in effective prevention of CD:
1. Development of new European guidelines for early nutrition in order to prevent the disease;
2. Identification of the influence of early feeding on the development of coeliac disease in relation with immunological and genetical factors.

Study description

Background summary

Title of the study:
Influence of the dietary history in the prevention of coeliac disease : possibilities of induction of tolerance for gluten in genetically predisposed children.

Background of the study:
Coeliac disease (CD) is a chronic disorder caused by hypersensitivity to some of the most common proteins (gluten) in the diet of the European population. CD affects as much as 1% of the Europeans (2.5 million people) and is the most common food intolerance in Europe. If recognised, CD patients have only limited access to safe foods and there is not causal therapy available. The proposed study is a multicenter European project PREVENTCD, founded by the European Commission FP-6-2005-FOOD-4B; Proposal/Contract no.: 036383.

The general objective of PREVENTCD is to significantly reduce the number of people suffering from CD in Europe, by developing primary prevention strategies for CD.

The hypothesis of the study is that it is possible to induce tolerance for gluten in genetically predisposed children through the introduction of small quantities of gluten during the period of breast-feeding.

Objective of the study:
1. Development of a prevention strategy for CD in children from high risk families for the disease by induction of oral tolerance to gluten;

2. Identification of the immunological mechanisms involved in initiating the aberrant response to gluten introduction in the diet of infants genetically predisposed to CD;
3. Identification of the factors in the early dietary history involved in the aberrant response to gluten in children;

Study design:
European, multicenter, double blind, prospective, randomised food intervention study

Study population:
1000 infants born from families with one parent or sibling with diagnosed CD.

Intervention:
The children bearing HLA-DQ2 and/or DQ8 will be blindly randomised to either a group for "tolerance induction for gluten" or to a "control" group. At least 6 months of breast-feeding will be STRONGLY encouraged for all the children.
At the age of 4 months tolerance induction will be attempted by the daily intake of 1g wheat flour (100 mg gluten) during 8 weeks while continuing breast-feeding. No gluten will be given in these 8 weeks to control infants, but 1g. lactose as a placebo intervention.
primair outcome:
A reduction of 50% of CD among the intervention group at the age of 3 years will be considered as an effective prevention.

Secondary outcome:
- If the proposed early dietary intervention results in effective prevention of CD: development of new European guidelines for early nutrition in order to prevent the disease.
- Identification of the influence of early feeding on the development of coeliac disease in relation with immunological and genetical factors.

Study objective

To induce tolerance for gluten in genetically predisposed children for coeliac disease through the introduction of small quantities of gluten during the period of breast-feeding.

Study design

-

Intervention

In the family study:
1. The ‘intervention group’ will get a small amount of gluten (1 gram of wheat flour= 100mg gliadin) during the period of breastfeeding from the age of 4 months for 8 weeks.
2. The ‘control group' (placebo) will get milk sugar powder (1gram of lactose) during the period of breastfeeding from the age of 4 months for 8 weeks.

Contacts

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Eligibility criteria

Inclusion criteria

1.Infant born during the study with a first degree relative (parent or sibling) with CD;
2.Informed consent for the study.

Exclusion criteria

1. No informed consent;
2. Parents-guardians unable to understand the information necessary to give informed consent.

Study design

Design

Study type: Interventional

Intervention model:	Parallel
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-01-2007
Enrollment:	1000
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	08-02-2007
Application type:	First submission

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
NTR-new	NL876
NTR-old	NTR890

Register	ID
Other	- : N/A
ISRCTN	ISRCTN74582487

Study results

Summary results

Statistical Analysis Plan, 74582487, August 1st, 2013, Prof.dr.H. Putter, Dr. M. L. Mearin, Sabine Vriezinga
http://preventcd.com/images/stories/Publications/PreventCD_SAP_1_0.pdf