

Influence of the dietary history in the PREVENTion of Coeliac Disease: possibilities of induction of tolerance for gluten in genetic predisposed children

Submission date 26/02/2007	Recruitment status No longer recruiting	☒ Prospectively registered ☐ Protocol
Registration date 26/02/2007	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 27/05/2021	Condition category Digestive System	☐ Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number

NTR890

Study information

Scientific Title

Randomized Feeding Intervention in Infants at High Risk for Celiac Disease

Acronym

PREVENTCD

Study objectives

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.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approval received from the Leiden University Medical Centre (LUMC), Commissie Medische Ethiek on the 1st December 2006 (ref: P06.177). Also the ethical review of the project received a positive opinion from the European Commission; the Commission of the European Communities - Research Directorate - General (Directorate E- Biotechnology, Agriculture and Food research) on the 11th September 2006 (ref: FOOD-CT-2006-36383).

Each partner in the PREVENTCD project has the approval of their local medical ethics board.

Study design

Randomised placebo-controlled parallel-group double-blinded multicentre trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Coeliac disease

Interventions

In the family study:

1. The intervention group will get a small amount of gluten (1 gram of wheat flour = 100 mg gliadin) during the period of breastfeeding from the age of four months for eight weeks
2. The control group (placebo) will get milk sugar powder (1 g of lactose) during the period of breast feeding from the age of four months for eight weeks

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

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

Key secondary outcome(s)

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

Completion date

31/12/2011

Eligibility**Key inclusion criteria**

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

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Child

Sex

All

Total final enrolment

944

Key exclusion criteria

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

Date of first enrolment

26/05/2007

Date of final enrolment

10/09/2013

Locations

Countries of recruitment

Croatia

Hungary

Israel

Italy

Netherlands

Poland

Spain

Study participating centre

Leiden University Medical Centre

Leiden

Netherlands

2300 RC

Sponsor information

Organisation

Leiden University Medical Centre (LUMC) (The Netherlands)

ROR

<https://ror.org/027bh9e22>

Funder(s)

Funder type

Government

Funder Name

European Commission (Belgium)

Alternative Name(s)

European Union, Comisión Europea, Europäische Kommission, EU-Kommissionen, Euroopa Komisjoni, EC, EU

Funding Body Type

Government organisation

Funding Body Subtype
National government

Location

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	02/10/2014		Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes