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

Recruitment status No longer recruiting	[X] Prospectively registered		
	☐ Protocol		
Overall study status	Statistical analysis plan		
Completed	[X] Results		
Condition category Digestive System	[] Individual participant data		
	No longer recruiting  Overall study status  Completed		

## Plain English summary of protocol

Not provided at time of registration

# Contact information

# Type(s)

Scientific

#### Contact name

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#### Contact details

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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

# 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

**Funding Body Type**Government organisation

Komisjoni, EC, EU

Countries of recruitment

Croatia

# 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