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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	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 26/02/2007	**Overall study status** Completed	
Last Edited 27/05/2021	**Condition category** Digestive System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

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.

Primary study design
Interventional

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

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