Tolerance induction in cow's milk allergy

Published: 08-04-2008
Last updated: 08-05-2024

The project is focused on induction of immune tolerance in allergy by prebiotics. The pathophysiology of immune modulation will be investigated and searched for potential biomarkers for immune modulation.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Allergic conditions
Study type	Interventional

Summary

ID

NL-OMON30721

Source
ToetsingOnline

Brief title
Tolerance induction in cow's milk allergy

Condition

- Allergic conditions

Synonym
Cow's milk allergy/ Cow's milk protein allergy

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Het onderzoek maakt deel uit van een TI Pharma project.,Numico

Intervention

Keyword: Allergy, Immune tolerance, Prebiotics

Outcome measures

Primary outcome

The percentage of infants who develop tolerance at each outpatient day clinic visit (OPD), determined by a DBPCFC.

Secondary outcome

The incidence and severity of asthma and allergic rhinitis.

Serum Total IgE, IgG and IgG4 concentration.

Newly acquired sensitizations, measured by specific IgE for the most prevalent food-and inhalant allergens.

Peripheral blood derived T-cell phenotype, antigen-specific proliferation and cytokine production and/or expression of intracellular transcription factors specific for regulatory T-cells and cytokine production.

Stool samples will be studied for identification and quantification of micro-organisms.

Study description

Background summary

Inflammatory diseases like allergies and autoimmune diseases are increasing in the Western world. These disorders are associated with a disturbed immune balance and lack of immunological tolerance. Therefore there is a wide interest in development of safe immune modulating therapies to correct for these disorders.
Intervention in early life will focus on promotion of a proper maturation of the immune system and prevention of inflammatory and autoimmune diseases. Later in life, specific immunotherapy is the only curative treatment left. Current knowledge indicates a key role for dendritic cells (DC) during initiation of adaptive cellular immunity. Depending on several factors, DCs direct T cell responses by either promoting T cell activation (Th1 or Th2 response) or by inducing tolerance (activation of regulatory T cells).

Recently is shown that the gastro-intestinal tract is one of the most essential factors for development of immune tolerance. Natural occurring candidates for tolerance induction are heat shock proteins (HSP) and oligosaccharides. Oligosaccharides and glycoproteins have demonstrated to promote Th1 activity and suppress occurrence of allergies and infections. The exact mechanisms is still not clear but a mixture of neutral galacto-oligosaccharides (GOS) and fructo-oligosaccharides (FOS) have been identified as effective prebiotic ingredients.

Study objective

The project is focused on induction of immune tolerance in allergy by prebiotics. The pathophysiology of immune modulation will be investigated and searched for potential biomarkers for immune modulation.

Study design

1. Double-blind, placebo-controlled, randomised trial with prebiotics in young children with cow*s milk allergy.
2. In vitro evaluation of immunologic effects of prebiotics in these children

Intervention

Oligosaccharides and glycoproteins mixed with hydrolysed formula or breastmilk.

Study burden and risks

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: Risks and burden for subjects are considered minimal and related to DBPCFC and blood withdrawals.
DBPCFC will be done during one of the OPD visits and under controlled circumstances.
Blood withdrawal will be done by experienced professionals.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

Child
Cow's milk allergy diagnosed by double blind, placebocontrolled randomised foodchallenge

Exclusion criteria

immune-mediated disease

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-07-2007
Enrollment:	90
Type:	Anticipated

Ethics review

Approved WMO

Date:	08-04-2008
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL16218.041.07