A randomised, double-blind, controlled, parallel-group, multi-country study to investigate the effect of a partially hydrolysed infant formula with added synbiotics on the development of allergic manifestations in infants at high risk of developing allergy.

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

Summary

ID

NL-OMON47293

Source
ToetsingOnline

Brief title
MAESTRO study

Condition

- Allergic conditions

Synonym
infants at high risk of developing allergy

Research involving
Human

Sponsors and support

Primary sponsor: Nutricia
Source(s) of monetary or material Support: Nutricia Research BV

Intervention

Keyword: Allergy prevention, Infant Formula/ Follow on Formula, Partially hydrolysed protein, Synbiotics

Outcome measures

Primary outcome

This study investigates the effect of HP synbiotics compared to standard infant formula on the development of allergic manifestations up to the age of 12 months in infants at high risk of developing allergy.

The primary outcome parameter will be chosen based on the results of an independent study (TEMPO). The choice will be implemented during the interim analysis (see protocol section 10) and documented in an administrative protocol amendment.

Secondary outcome

To investigate the effect of HP synbiotics compared to standard infant formula on the development of growth, safety, allergic manifestations (immune and/or microbiota parameters in faeces, blood and saliva) up to the age of 12 months in infants at high risk of developing allergy.

Study description

Background summary

Over the past decades, the prevalence of allergic disorders has increased exponentially around the world with variation in physical location of the manifestation (skin, lung, GI tract) dependent on geographical spread. With the increased prevalence of allergic disease and the deriving risk of the development of other immune related diseases, primary prevention from allergies has become an important priority. Many studies have been conducted to investigate and develop primary prevention from allergies using nutrition in children with a high risk of developing allergic disease.

It is generally acknowledged that breastfeeding is one of the main pillars in allergy prevention. Many studies have examined the benefits of breastfeeding on the development of allergic disease. From these studies, it can be concluded that breastfeeding up to 4-6 months decreases the risk of atopic dermatitis in infants at increased risk. When a mother is unable or chooses not to breastfeed her infant, an infant formula based on the composition of human milk is recognized as the best alternative. For infants at increased risk to develop allergy a partially hydrolysed cow*s milk protein formula is developed.

A German and Australian study and a study conducted by Nutricia Research (PATCH), which investigated the use of hydrolysed formula, show a minor short term effect beside a long term decrease of allergic disease in children with a high risk. However eczema and food allergies are the most common allergic manifestations in the first 2 years, eczema turns out to be more of an indicative risk factor for allergic sensitization due to a changed skin barrier than a symptom of allergy. Therefor additional studies in children with a high risk of developing allergic disease is needed, to confirm the possible effects of pHF on the reduction of allergic symptoms.

Study objective

This study investigates the preventive action of formula with partially hydrolysed cow milk protein supplemented with pre- and probiotics in the development of allergy. The goal of the study is to investigate the efficacy, the growth and the safety of the hypo allergen formula in children whom can develop allergy or allergic manifestations in the first 52 weeks of their life compared to normal formula.

Study design

This is a randomised, double blind, controlled, parallel-group, multi-country study.

Intervention

Active product: Formula /follow-up formula with partially hydrolysed whey protein supplemented with prebiotics and probiotics (HP synbiotics)

Control product: standard formula/follow-up formula (complete protein)

Study burden and risks

No adverse events are expected in the active formula/ follow-up formula (HP synbiotics) or control formula/follow-up formula, except the expected overall interaction with food as stated on the label. The use of probiotics is associated with softer stools (where it looks more like the stools of breastfed infants). The test product contains cow milk proteins. These proteins can cause an allergic reaction in children with a cow milk, soya protein, cow meat, corn or fish protein allergy. The taking of a blood sample can give mild pain, cause a bruise, an inflammation of the vein, hemorrhage or infection of the place where the needle has gone into the skin and rarely can cause nerve damage. Taking a nasal swab may cause temporary discomfort. Filling in the diary will cost extra time for parents. The skin prick test can cause discomfort and mild red skin and itching of the skin punctured specify which usually disappears within hours.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

1) Healthy term infants (gestational age * 37 and * 42 weeks) at high risk of developing allergy based on family history of allergy.;2) Infants aged * 16 weeks (max. 16 weeks + 0 days), preferably as soon as possible after birth.;3) Infants with birth weight within normal range for gestational age and sex (10th to 90th percentile according to local applicable growth charts).;4) Infants who start formula feeding within 16 weeks of age (infants of mothers who have chosen not to breastfeed or mothers who completely/partially cease breastfeeding before the subject*s age of 16 weeks)
OR
Infants who are exclusively breastfed and whose mothers have the intention to exclusively breastfeed at least until their infant is 16 weeks of age.;5) Written informed consent from one or both parents (according to local laws) and/or legal guardian.

Exclusion criteria

1) Consumption of any amount of infant formula based on intact protein before randomisation.;2) Consumption of any amount of infant formula with added probiotics and/or probiotic supplement before randomisation.;3) Existing allergic manifestations (e.g. allergic skin disorders, food allergy) before randomisation according to investigator*s clinical assessment.;4) Severe congenital abnormalities which could influence the subjects* growth (e.g. cystic fibrosis, bronchopulmonary dysplasia, tracheomalacia, tracheoesophageal fistula, major congenital heart disease, or any other condition according to investigator's clinical judgement).;5) Severe neonatal illnesses (e.g. respiratory distress syndrome, severe sepsis intraventricular hemorrhage, severe neonatal jaundice, necrotizing enterocolitis, persistent pulmonary hypertension of the newborn, or any other condition which required the use of intravenous antibiotic).;6) Known underlying disease predisposing to infection (e.g. HIV, viral hepatitis B, and C, auto-immune diabetes, immune deficiency).;7) Severe renal failure and hepatic failure according to investigator's clinical judgement.;8) Incapability of the parents to comply with study protocol or investigator's uncertainty about the willingness or ability of the subject to comply with the protocol requirements;9) Participation in other studies involving investigational or marketed products

concomitantly or within two weeks prior to screening visit.

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-05-2017
Enrollment:	212
Type:	Anticipated

Ethics review

Approved WMO Date:	24-01-2017
Application type:	First submission
Review commission:	IRB Nijmegen: Independent Review Board Nijmegen (Wijchen)
Approved WMO Date:	08-03-2017
Application type:	Amendment
Review commission:	IRB Nijmegen: Independent Review Board Nijmegen (Wijchen)
Approved WMO Date:	07-09-2017

Application type:	Amendment
Review commission:	IRB Nijmegen: Independent Review Board Nijmegen (Wijchen)
Approved WMO Date:	28-12-2017
Application type:	Amendment
Review commission:	IRB Nijmegen: Independent Review Board Nijmegen (Wijchen)
Approved WMO Date:	03-05-2018
Application type:	Amendment
Review commission:	IRB Nijmegen: Independent Review Board Nijmegen (Wijchen)

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
ClinicalTrials.gov	NCT03062995
CCMO	NL59596.072.16