A Randomized, controlled, cross-over Study to assess Hypoallergenicity of an extensively hydrolyzed whey protein Infant formula in children with cow's milk allergy using amino-based infant formula as a reference.

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

Summary

ID

NL-OMON41369

Source
ToetsingOnline

Brief title
SHINE

Condition

- Allergic conditions

Synonym
Cow's Milk Allergy, Cow's milk proteïne allergy

Research involving

Human

Sponsors and support

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

Intervention

Keyword: cow's milk allergy, hypoallergenicity, infant formula

Outcome measures

Primary outcome

Incidence of immediate and/or delayed allergic reactions.

Secondary outcome

Anthropometrics, gastro-intestinal tolerability and faecal characteristics.

Blood safety and tolerance parameters.

Study description

Background summary

Nutricia Research recently developed an upgrade to their existing extensively hydrolyzed formula, based on an extensively hydrolyzed whey proteins. The formula has been enriched.

The recently developed new formula has a peptide distribution of all peptides in size below 3000 Dalton. Althought the American Academy of Pediatrics (AAP) defines an extensively hydrolyzed formula as a formula that contains only peptides that have a molecular weight of less than 3000 Dalton, there is no clear evidence that such a threshold would ensure to prevent from provoking allergic reactions in infants and young children with cow's milk allergy. Therefore, after appropriate preclinical testing, hypoallergenic formulas must demontstrate in clinical studies that with 95% confidence they do not provoke allergic reactions in 90% of infants or children with confirmed cow's milk allergy.

Study objective

The primary study objective is to assess the hypoallergenicity of an extensively hydroloyzed whey protein infant formula in children with cow's milk allergy.
The second study objective is to assess the long-term effects on growth and tolerance of an extensively hydrolyzed whey protein infant formula in children with cow's milk allergy.

Study design

This is a prospective, controlled, multi-country study. Phase A includes a DBPCFC (double blind placebo controlled food challenge) which involves a crossover procedure. Additionally phase A includes an open challenge with a single-arm design. Phase B is optional and designed as an open-label, single-arm study.

Intervention

Test procuct: the upgrade of an extenstensively hydrolized formula based on extensively hydrolyzed whey proteins.
Reference product: Neocate.

Patients will take both products, each on one of the two Provocation test days. Next to that the test product will be taken open label during one week.

If a patient participates in fase B, the testproduct will be taken open label during 16 weeks.

Study burden and risks

DBFCs, which are performed during this study, are considered as the 'gold standard' for the diagnosis of food allergies for over 20 years. In this study DBPCFCs are performed in specialized centres by experienced staff according to controlled procedures; adverse reactions, such as eczema, asthmatic symptoms and urticaria, to DBPCFCs could occur.
Children with a history of anaphylactic reactions will be excluded for participation.

The blood samples during this study are collected by appropriately trained staff. This may be slightly painful to the subject and may induce some local bruising. Anesthetic cream will be applied to the skin before taking the blood sample.

Measurements taken to treat any unexpected severe allergic reactions adequately, i.e. anafylactische shock is described in Appendix III, #3 of the protocol: Intramuscular adrenaline, inhaled bronchodilator, oral or intravenous antihistamine, orale of intravenous corticosteroids should be available during

DBPCFC, for immediate use. According to standard medical care and procedures.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

- Children with a documented cow's milk allergy.
- Between birth and 3 years of age.
- Expected daily intake of at least 250ml of the study product during the open challenge.

Exclusion criteria

- Children who receive breastfeeding more than twice daily during the week before inclusion.
- Confirmed history of anaphylactic reaction, including severe cardiovascular symptoms,

severe laryngeal edema, and bronchus obstruction.
- Intolerance for lactose or any other component of the study product(s).
- Previous signs of allergy to any extensively hydrolyzed formula.
- Previous use of an amino acid formula due to (suspected) severe cow's milk allergy.
- Major congenital malformations.
-Investigator's uncertainty about the willingness or ability of the parents to comply with the protocol requirements.

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-10-2012
Enrollment:	18
Type:	Anticipated

Ethics review

Approved WMO Date:	16-10-2012
Application type:	First submission
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	07-01-2013

Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	07-11-2013
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	02-04-2014
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	15-04-2014
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	24-06-2015
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 21357
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL41090.075.12
OMON	NL-OMON21357