Study to test a new infant formula for cow's milk allergic infants

Published: 01-07-2013
Last updated: 15-05-2024

At least 90% of the subjects, with 95% confidence, will tolerate the test formula.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	Allergic conditions
Study type	Interventional

Summary

ID

NL-OMON21357

Source
Nationaal Trial Register

Brief title
SHINE

Condition

- Allergic conditions

Health condition

Children with cow's milk allergy.

Research involving
Human

Sponsors and support

Primary sponsor: Nutricia Research BV
Source(s) of monetary or material Support: Danone Research - Centrre for Specialised Nutrition

Intervention

- Food (substances)

Explanation

Outcome measures

Primary outcome

Incidence of immediate and/or delayed allergic reactions to the DBPCFC and/or a subsequent open challenge with the test product during phase A of the study.

Secondary outcome

- Anthropometrics

- Gastro-intestinal tolerability (e.g. abdominal cramps)

- Faecal characteristics (stool frequency/consistency)

Study description

Background summary

Participation in this study will be voluntary and written informed consent will be obtained from one or both parents (depending on the local legislation) or legal representative.

Screening will take at least one week and one hospital visit. During the screening visit(s) subject characteristics, family characteristics, and relevant medical history will be recorded and data on anthropometrics will be collected. For subjects with a non-confirmed/diagnosed cow’s milk allergy (>2 months), the diagnosis of cow’s milk allergy (according to inclusion criteria) will be part of the screening assessment. A blood sample (5ml) to determine serum IgE levels (total and cow’s milk protein specific) and (optionally) blood safety parameters will be drawn either during the screening visit or the first challenge day.

At least 25 evaluable subjects with proven cow’s milk allergy will be enrolled in this study. The study will start after the subject has been free of clinical symptoms or with controlled stable symptoms for at least one week (elimination period; it may take some weeks before this stable phase will be reached).

The DBPCFC includes two separate visits within a 1-week time frame; subjects receive the test product and the reference product in random order over the two separate visits. Acute allergic reactions are monitored during the challenge day in the hospital. Any delayed allergic reactions during 1 week following the challenge will be collected by a call of the investigator to the parents (Phone call 1) If needed, exacerbation of eczema will be verified by physical examination in the hospital. At the first of these two visits, data on anthropometrics and recent GI symptoms are collected. At the end of the last visit of the DBPCFC, test products for the open challenge are provided.

If the subject does not show any allergic symptoms after the DBPCFC with the study products, the investigator will allow continuation with the open challenge. The subject consumes the test product for one week. During this week, the subject should consume at least 250ml per day of the test product and the parents will record the product intake. In case of an INCONCLUSIVE result, parents are asked to allow repetition of phase A. If not, the subjects' participation in the study is discontinued.

At the fourth hospital visit, allergic symptoms will be evaluated and remaining questions and experiences of the subject's parents will be discussed.

In case the subject continues with phase B (optional) of the study, the subject will continue on the test product (open-label) for 16 weeks. The preference is that the subject will consume at least 250ml test product. Phase B shall be overseen by a specialist team (e.g. pediatrician, dietician) in order to provide the subject's parents with nutritional expertise while feeding on the test product. (e.g. regarding the introduction of solid food).

At Visit 4 and Visit 5 data on anthropometrics will be collected, and test product will be distributed. Diaries will be distributed in order to collect data on gastrointestinal tolerability on a weekly basis. A blood sample (5ml, optional) will be drawn at visit 4 and visit 6. At the last visit (visit 6), data on anthropometrics will be collected and remaining test product, as well as completed diaries, will be collected. A FU call will be done by the investigator to the parents 2 weeks after study completion (visit 6 or early termination visit).

A maximum of 43 evaluable children will be included in the study. In case during phase A of the study no allergic reactions occur in the first 25 children, the trial is considered successful according to the AAP guidelines, and recruitment will be stopped. If allergic reactions occur, recruitment will be increased until 43 included subjects. However, early termination of the trial will take place, in case of 2 confirmed allergic reactions (and confirmed per-protocol) to

the test products during phase A of the study.

Study objective

At least 90% of the subjects, with 95% confidence, will tolerate the test formula.

Study design

Time points of the outcome: for example: V1 (screening); V2 (wk0); V3 (wk0+ 3-7 days); V4 (wk2); optional V5 (wk10) and V6 (wk18).

Intervention

Intervention group: New extensively hydrolysed infant formula.

Control group: Amino acid-based infant formula (reference)

Duration of phase A: 2 weeks; Double-blind placebo controlled food challenge, which involves a cross-over procedure. Additionally the study includes an open challenge with a single arm design.

Duration of phase B: 16 weeks; An open-label, single-arm study.

Contacts

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Eligibility criteria

Age
Newborns
Newborns
Babies and toddlers (28 days-23 months)
Babies and toddlers (28 days-23 months)
Children (2-11 years)
Children (2-11 years)

Inclusion criteria

- Children with a documented cow’s milk allergy, confirmed by one of the following criteria, within two months prior to first DBPCFC (visit 2):

o Positive double-blind, placebo-controlled oral food challenge (DBPCFC) with cow’s milk OR

o Positive open or single-blind oral food challenge with cow’s milk carried out under the supervision of a specialist in children with clear immediate reactions and a positive test for specific IgE (in serum or skin prick test).

- Aged < 36 months of age at screening.

- Expected consumption of a minimum of 250ml of study formula per day during the open challenge of Phase A.

- Written informed consent from one or both parents (depending on the local legislation) or legal representative.

Exclusion criteria

- Children who receive breastfeeding more than twice daily during the week before inclusion.

- Confirmed history of acute severe, potentially life threatening reaction after isolated accidental ingestion of cow’s milk e.g. history of anaphylactic reaction, including severe cardiovascular symptoms, severe laryngeal edema, and bronchus obstruction.

- Proven or existing intolerance for lactose or any other component of the study product(s).

- Previous use of an amino acid formula due to (suspected) severe cow’s milk allergy.

- Existing illness that could interfere with formula acceptance or identification of allergic reactions.

- Previous signs of allergy to any extensively hydrolyzed formula.

- Major congenital malformations according to the definition in this protocol.

- Investigator's uncertainty about the willingness or ability of the parents to comply with the protocol requirements.

- Participation in any other studies involving investigational or marketed products concomitantly or within two weeks prior to entry into the study.

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:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-10-2012
Enrollment:	25
Type:	Actual

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion

Date:	18-10-2012

Application type:	First submission
Review commission:	METC Isala klinieken Zwolle

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Study registrations

Followed up by the following (possibly more current) registration

ID: 41369
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL3889
NTR-old	NTR4051
Other	Nutricia Research : HYD.1.C/B
CCMO	NL41090.075.12
OMON	NL-OMON41369

Study results

Summary results
N/A