Reduction of cow’s milk protein allergy risk by using a formula with partially hydrolyzed whey protein.

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25443

Source
NTR

Brief title
A.R.T.

Health condition

risk reduction, cow's milk allergy

Sponsors and support

Primary sponsor: Dr. Rouzha Pancheva, Prof. Dr. Paraskev Stoyanov" Medical University of Varna, 55 "Marin Drinov" Str., 9002 Varna, Bulgaria
Dr Nicolaos Nicolaou, Asthma and Allergy Center LTD, 24 Nafpliou Street, St Raphael Court, 2nd floor, No. 21, 3025, Limassol, Cyprus
Dr. Nicoletta Iacovidou, Magginio Maternity Clinic, Aretaieio Hospital”, Athens, Greece
Source(s) of monetary or material Support: FrieslandCampina, Stationsplein 4, Amersfoort, The Netherlands

Intervention

Outcome measures

Primary outcome

Proven cow's milk protein allergy: atopic dermatitis and total allergic manifestations

Secondary outcome

Growth in weight, length and head circumference

Study description

Background summary

In the present multi-centre study the Cow’s Milk Allergy (CMA) risk reduction of apreventive HA (Hypo Allergenic) formula is studied in a high risk (based on family history of allergies) group of infants, as compared to standard infant formula and fully breast milk fed infants, during the first 6 months of life. During this period the infants will visit the researchers every month to evaluate growth and symptoms of allergy. In a follow up study at the ages of 8 and 12 months the incidence of allergic symptoms will be monitored by questionnaires, whereas growth will be measured at the age of 12 months. This part of the study (2nd half year of life) however will be analyzed separately and is not part of the present main study.

The design of the present study is in particular based on the German Infant Nutritional Intervention Study (GINI). The read-outs of this study will be: 1) allergic/atopic manifestations (all manifestations and atopic dermatitis in particular) to show the product’s efficacy, and 2) growth (weight, length, head circumference) for safety and suitability of the product. In case of allergic/atopic manifestations, a proper diagnosis will take place.

Study objective

The preventive HA formula will show on average a 40% risk-reduction for AD (54% when AD is not present in family history and 22% when AD is present in the family history) as compared to a standard formula.

2) The preventive HA will show a 30% risk reduction for total allergic manifestations, as compared to standard formula.

Study design

Monthly visits during the first half year of life, and follow up at the age of 8 and 12 months using questionnaires.

Intervention

Partially hydrolyzed protein formula during the first 6 months of life. Control groups are standard infant formula and fully breast fed infants

Contacts

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Eligibility criteria

Inclusion criteria

• Gestational age ≥37 weeks

• Younger than 5 days (with regard to time to decide on participation)

• At least one of the parents or siblings has or had a documented allergy.

• Apparently healthy, no symptoms of allergy.

• Being breast fed or provided with extremely hydrolyzed formula from birth onwards

• Being available for follow up until the age of 6 months

• Willing to fill in two questionnaires at infant’s age of 8 and 12 months

• Written informed consent

Exclusion criteria

• Severe acquired or congenital diseases, mental or physical disorders, symptoms of allergy according to the SCORAD or ComiSS forms

• Gestational age <37 weeks

• Birth weight <2500 g

• Age >4 days

• No parents or siblings with documented allergy

• Infants who have been fed standard or partially/extensively hydrolyzed infant formula other than extremely hydrolyzed formula during the days of life.

• Incapability of parents to comply with the study protocol.

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-04-2017
Enrollment:	750
Type:	Anticipated

Ethics review

Not applicable
Application type: Not applicable

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
NTR-new	NL6120
NTR-old	NTR6259
Other	: GND-02-2016

Study results