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

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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...

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON25443

Bron
Nationaal Trial Register

Verkorte titel
A.R.T.

Aandoening

risk reduction, cow's milk allergy

Ondersteuning

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Overige ondersteuning: FrieslandCampina, Stationsplein 4, Amersfoort, The Netherlands

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

• 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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

• 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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-04-2017
Aantal proefpersonen:	750
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort: Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL6120
NTR-old	NTR6259
Ander register	: GND-02-2016

Resultaten