Study to assess the effect of an added Synbiotic mixture on Atopic dermatitis in INfanTs.

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A positive effect of using test product with respect to the change of SCORAD after 4 months of intervention in subjects with atopic dermatitis.

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON23678

Bron
NTR

Verkorte titel
SAINT

Aandoening

Atopic Dermatitis

Ondersteuning

Primaire sponsor: This clinical study will be performed within TOP Institute Pharma (project T1-501). Besides Danone Research, also the Academic Medical Center (AMC) Amsterdam, Wilhelmina Children's Hospital (WKZ) Utrecht, VU University Amsterdam, and the Utrecht Institute for Pharmaceutical Sciences (UIPS) will participate in the TOP Institute Pharma project. Danone Research shall take care of the Sponsor responsibilities as defined by ICH-GCP'.
Overige ondersteuning: This trial is funded by Top Institute Pharma (40%; cash), industry (40%; 1/2 cash, 1/2 in-kind) and Academy (20%; in-kind). There are several partners involved. The industrial partner is Danone Research. The Academice partners are Academic Medical Center (AMC) Amsterdam, Wilhelmina Kinder ziekenhuis (WKZ) Utrecht, VU Universiteit Amsterdam and Utrecht Institute for Pharmaceutical Sciences (UIPS).

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary outcome parameter in this study is the change of SCORAD after 4 months of intervention.

Toelichting onderzoek

Achtergrond van het onderzoek

In this study the effect of an added synbiotic mixture in infant formula compared to infant formula without a synbiotic mixture will be assessed in children with atopic dermatitis. After screening subjects will be randomly allocated to receive either the infant formula with synbiotics or the infant formula without synbiotics for a period of 16 weeks. During this intervention period parents will be contacted by phone 3 times every 4 weeks to check how the subject is doing. In case of the occurrence of exacerbations of AD in the subjects during the study the parents will be asked to visit the hospital. After the 16 weeks intervention, the parents will visit the hospital for a final check.

Doel van het onderzoek

A positive effect of using test product with respect to the change of SCORAD after 4 months of intervention in subjects with atopic dermatitis.

Onderzoeksopzet

Screening (week -2), Baseline (week 0), Phone call 1 (week 4), Phone call 2 (week 8), Phone call 3 (week 12), End of study visit (week 16).

Onderzoeksproduct en/of interventie

Duration of intervention: 4 months.

Intervention group: Receiving an extensively hydrolyzed whey protein based infant formula with a synbiotic mixture (≥ 500ml/day) for a period of 4 months.

Control group: Receiving an extensively hydrolyzed whey protein based infant formula without a synbiotic mixture (≥ 500ml/day) for a period of 4 months.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Infants/children with atopic dermatitis;

2. Between 0-8 months of age;

3. Expected daily intake of at least 500ml of the study product;

4. Written informed consent of both parents / legal representative(s).

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Intolerance for any other component of the study product(s);

2. History of anaphylactic reaction to cow's milk protein, including severe cardiovascular symptoms (shock), severe laryngeal edema, and bronchus obstruction;

3. Use of antihistamines prior to (48 hours) the study;

4. Use of oral steroids prior to (4 weeks) the study;

5. Use of antibiotics or anti-mycotic drugs prior to (4 weeks) the study;

6. History or presence of cardiovascular, gastrointestinal, hepatic, renal or respiratory chronic disease other than allergy;

7. Major congenital abnormalities;

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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	07-06-2012
Aantal proefpersonen:	144
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	22-05-2012
Soort:	Eerste indiening

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	NL3279
NTR-old	NTR3447
Ander register	Top Institute Pharma : SYN.3.C/A
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
Hulshof L, Overbeek SA, Wyllie AL, Chu MLJN, Bogaert D, de Jager W, Knippels LMJ, Sanders EAM, van Aalderen WMC, Garssen J, Van ’t Land B, Sprikkelman AB. Exploring Immune Development in Infants With Moderate to Severe Atopic Dermatitis. Front Immunol., 2018;9:630.