The effect of early nutrition in high-risk infants on allergy prevention during the first 12 months of life.

Extension: The effect of nutrition given in the first 6 months of life in high-risk infants on allergy prevention up to 7 years of age.

Gepubliceerd: 13-12-2005 Laatst bijgewerkt: 18-08-2022

It is expected that feeding a new hypoallergenic formula will result in a lower occurrence of AEDS (Atopic Eczema Dermatitis Syndrome) compared to giving a standard formula in infants with a high risk of developing atopic disease. Extension: To...

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON26735

Bron
NTR

Verkorte titel
PATCH

Aandoening

Infants with a high risk classification for atopic disease

Ondersteuning

Primaire sponsor: Numico Research B.V.
Numico Research B.V.
Bosrandweg 20
P.O. Box 7005
6700 CA Wageningen
The Netherlands
+31 (0) 317 467 800
Overige ondersteuning: Numico Research B.V.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Main study:
Cumulative incidence of AEDS. Diagnosis according to modified Hanifin and Rajka criteria and SCORAD index of 10 or higher.

Extension:
Cumulative incidence of allergic manifestations (atopic dermatitis, food allergy, allergic rhinitis, allergic conjunctivitis, allergic urticaria and allergic asthma) based on physician’s diagnosis.

Toelichting onderzoek

Achtergrond van het onderzoek

This double blind placebo controlled trial has been designed to compare feeding a newly developed hypoallergenic formula with feeding a standard formula during the period of age 0-1 months until 6 months to babies with an increased risk to develop allergy. It is expected that the new hypoallergenic formula will result in a lower occurrence of eczema until the age of 12 months and 18 months compared to giving standard formula. Results will also be compared to an exclusively breastfed group.

Extension:

The prevalence of allergic diseases in childhood strongly increased in the Western world over the past 20-30 years. A cumulative prevalence of 25-30% has been reported, with high

incidences of both atopic dermatitis and asthma. Atopic dermatitis is mainly seen in infancy, whereas asthma develops later in childhood. However, sensitisation in early years appears to be associated with increased sensitivity in later childhood.
The PATCH-study was initiated to investigate the clinical efficacy of a novel infant formula intended for the exclusive nutrition of high atopy risk infants that cannot be breastfed for various reasons.

Evidence is accumulating that nutritional influences in early life have long-term consequences for health and well-being in later life. Therefore this follow-up study will investigate the effect of early nutrition in the first 6 months of life on the development of allergic manifestations up to 7 years of age.

This study involves the follow-up of subjects who participated in and completed the PATCH study, without any nutritional intervention. In total 7 visits will take place and in between 11 phone calls.

Doel van het onderzoek

It is expected that feeding a new hypoallergenic formula will result in a lower occurrence of AEDS (Atopic Eczema Dermatitis Syndrome) compared to giving a standard formula in infants with a high risk of developing atopic disease.

Extension: To investigate the efficacy of a partially hydrolysed whey protein infant formula in high-risk infants on the prevalence of allergic manifestations (atopic dermatitis, food allergy, allergic rhinitis, allergic conjunctivitis, allergic urticaria and allergic asthma) between 2-3 years and 7 years of life compared to standard infant formula.

Onderzoeksopzet

Extension:

Time points of the outcome: The whole study will take around 6 years.

Visit 1: Screening;

Visit 2: 2 years of age; Baseline, sometimes combined with screening. Baseline measurements;

Visit 3: 3 years of age, major clinical visit;

Visit 4: 4 years of age ,telephone contact;

Visit 5: 5 years of age, major clinical visit;

Visit 6: 6 years of age, major clinical visit;

Visit 7: 7 years of age, major clinical visit;

Phone calls at 4 and 8 months between yearly contacts.

Onderzoeksproduct en/of interventie

Nutritional intervention starting between the age of 0 to 28 days after birth with formula feeding until the age of 26 weeks in a double-blind, randomised, parallel manner. The study will also include a group of exclusively breastfed infants.

The extension is an observational study. No randomisation will take place. Planned startdate is September 2010 and planned closingdate September 2016. The number of participants of the amendment is around 700.

Contactpersonen

Publiek

Numico Research B.V.
P.O. Box 7005
Dineke Klaassen
Bosrandweg 20
Wageningen 6700 CA
The Netherlands

Wetenschappelijk

Numico Research B.V.
P.O. Box 7005
Dineke Klaassen
Bosrandweg 20
Wageningen 6700 CA
The Netherlands

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Main criteria:

New born infants, high risk classification for atopic disease (at least one of the parents with documented allergic disease).

Extension:

1. Participation in and completion of the PATCH-study;

2. Written informed consent;

3. Aged between 2 (- 4 weeks) and 3 years (+ 4 weeks).

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Main criteria:

Premature delivery, twins, neonatal illnessess, significant congenital abnormalities, intake of cow's milk based formula before randomisation.

Extension:

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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Blindering:	Dubbelblind

Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	31-01-2006
Aantal proefpersonen:	1200
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	13-12-2005
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	NL506
NTR-old	NTR548
Ander register	: N/A
ISRCTN	ISRCTN65195597

Resultaten

Samenvatting resultaten
N/A