

The role of pre- and probiotics in infections in term infants.

Gepubliceerd: 23-10-2008 Laatste bijgewerkt: 18-08-2022

Supplementation of infant formula with a combination of pre- and probiotics may protect infants against infectious complications such as diarrhoea and respiratory infections. We speculate that the combination of pre and probiotics is better...

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

Samenvatting

ID

NL-OMON26255

Bron

NTR

Verkorte titel

HIPPO

Aandoening

Healthy term infants with intercurrent diseases: diarrhoea and respiratory infections.

Ondersteuning

Primaire sponsor: Sponsor: Dr R te Biesebeke

Global Development Centre

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Overige ondersteuning: Fund = initiator = sponsor

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

- Frequency, incidence and duration of diarrhoea and respiratory infections
composition of gut flora

Toelichting onderzoek

Achtergrond van het onderzoek

We speculate that the combination of pre and probiotics is better protective than only one of these substances. Supplementation of the combination of pre- and probiotics may reduce the incidence of infections to the same level as human milk fed infants.

Supplementation of infant formula with a combination of pre- and probiotics may protect infants against infectious complications such as diarrhoea and respiratory infections.

Doel van het onderzoek

Supplementation of infant formula with a combination of pre- and probiotics may protect infants against infectious complications such as diarrhoea and respiratory infections. We speculate that the combination of pre and probiotics is better protective than only one of these substances. Supplementation of the combination of pre- and probiotics may reduce the incidence of infections to the same level as human milk fed infants.

Onderzoeksopzet

1 - Frequency, incidence and duration of diarrhoea and respiratory infections, feeding tolerance : 2 weekly

2 - Antropometry: t=0, T = 3 and T=6 mths

3 - Fecal samples: T=0, T=3 and T=6 months

Onderzoeksproduct en/of interventie

Supplementation of infant formula with an combination of pre- and probiotics.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Healthy term infants with a postmenstrual age of 37-42 weeks
2. Birth weight between P10 and P90
3. Informed consent of both parents

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Neonatal sepsis
2. Severe congenital malformations
3. Birth asphyxia (apgar < 6 at 5 minutes, and/or umbilical cord pH < 7.00 and/or necessity of reanimation)
4. Admission to a pediatric ward
5. No Dutch or English speaking parents
6. Antibiotics to the mother during labour
7. Antibiotics to the infant in the first week of life
8. History of allergy with parents or sibs

Onderzoeksopzet

Opzet

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

Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	04-01-2007
Aantal proefpersonen:	225
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum: 23-10-2008

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	NL1442
NTR-old	NTR1503
Ander register	: 06-1178
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten

- 1) Effect of supplementation of infant formula with a a combination of pre- and probiotics on incidence and duration of infectious complications in term infants.

- 2) Effect of supplementation of of infant formula with a a combination of pre- and probiotics on the composition of gut flora.