The microflora in milk from mothers and the gastro-intestinal tract of their infants.

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The administration of probiotics to breastfeeding females exert a direct influence on the development of the infant gut microflora through the transference of selected strains.

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

Samenvatting

ID

NL-OMON25185

Bron
Nationaal Trial Register

Verkorte titel
ANIKA

Aandoening

Gut health, Infant gut microflora, Composition of the microflora of breast fed children as a biomarker, microbial biomarkers in human milk.

Ondersteuning

Primaire sponsor: Friesland Foods (Sponsor), Friesland Foods Anika Russia, Institute of Nutrition in Moscow (performer).
Overige ondersteuning: Friesland Foods (Anika Russia)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

- Effect of probiotic consumption of a breast feeding mother on the fecal microflora composition of the child
- Relation microflora of mothermilk and microflora of breastfed infants

Toelichting onderzoek

Achtergrond van het onderzoek

The indigenous microflora appears to be especially relevant in infants that develop a microflora balance in the lumen of the GI-tract during first months of life. Next to improvement of the mucosal barrier function, the microflora population in the GI-tract is enhanced by the generation of immunophysiologic regulation in the gut.
This has led to the introduction of novel therapeutic interventions based on the consumption of cultures of beneficial live microorganisms that act as probiotics.
There seems to be some preliminary evidence that oral and/or gut bacteria can enter the uterine environment suggesting that the gastrointestinal tract not only functions as a barrier against antigens from microorganisms and food but that the barrier is also involved in the selective passage of micro-organisms to the blood.
Although highly speculative, this would mean that the administration of probiotics to pregnant females might exert a direct influence on the development of the infant gut microflora through the transference of selected strains to neonates. In addition, breast milk has been suggested as an important factor in the initiation, development and composition of the neonatal gut microflora. Up to date several scientific papers have suggested that breastmilk might be the source of commensal and/or potential probiotic bacteria, since bacteria commonly isolated from breastmilk include staphylococci, streptococci, micrococci, lactobacilli and enterococci.

Doel van het onderzoek

The administration of probiotics to breastfeeding females exert a direct influence on the development of the infant gut microflora through the transference of selected strains.

Onderzoeksopzet

2, 4, 6 weeks after birth

Onderzoeksproduct en/of interventie

A group of healthy lactating women will consume a capsule of probiotics and a group of healthy lactating women will consume a placebo. The reference group will receive no supplementation at all during 6 weeks.

1. Study intervention

- Nutrition: the probiotic product is the commercially available FERROSAN probiotic powder.

- The different intervention groups

A) Reference: 30 breastfeeding mother/child pairs.

B) Placebo: 10 breastfeeding mothers consuming placebo (powder dissolved in boiling milk, consumed after cooling)

C) Treatment: 10 breastfeeding mothers consuming probiotic powder supplemented milk.

2. Samples

A) Mothers Breastmilk (5-10 ml) at 4 and 6 weeks of study

B) Infant fecal samples (ca. 5g) after receiving 4 and 6 weeks of breastfeeding (at least 75%) and 2, 4 and 6 weeks in case of the reference group.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Mother/child pair of which the mother delivered through natural birth.

2. Mother/child pair of which the infant is breast fed for at least 6 weeks.

3. Mothers and children without any clinical aberrancy.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Mother/child pair with formula fed children.

2. Mother/child pair of which the child was delivered through cesarian section.

3. Mothers consuming probiotics preparations/drinks/etc. other then supplied in the studie.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm

Blindering:	Enkelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-07-2007
Aantal proefpersonen:	60
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	03-09-2008
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	NL1367
NTR-old	NTR1427
Ander register	: IRCT010707
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten
Effect of consumption of Probiotics by Breastfeeding Mothers on the Fecal Microflora of Infants.