

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

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25185

Source

Nationaal Trial Register

Brief title

ANIKA

Health condition

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

Sponsors and support

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

Source(s) of monetary or material Support: Friesland Foods (Anika Russia)

Intervention

Outcome measures

Primary outcome

- 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

Secondary outcome

- pH of fecal samples
- Immunoglobulins in fecal samples and breast milk

Study description

Background summary

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.

Study objective

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.

Study design

2, 4, 6 weeks after birth

Intervention

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.

Contacts

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Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Single blinded (masking used)

Control: Placebo

Recruitment

NL
Recruitment status: Recruiting
Start date (anticipated): 01-07-2007
Enrollment: 60
Type: Anticipated

Ethics review

Positive opinion
Date: 03-09-2008
Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL1367
NTR-old	NTR1427
Other	: IRCT010707
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results

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