

Relationship between synbiotic components in the diet of atopic mothers and the synbiotic composition of breast milk. A hypothesis generating study.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON27416

Source

NTR

Brief title

Synbio-Breast

Health condition

Allergic disease

Sponsors and support

Primary sponsor: OLVG

Source(s) of monetary or material Support: OLVG and Nutricia Research

Intervention

Outcome measures

Primary outcome

the amount of lactobacillae/ml in mature breast milk (logCFU), 4 weeks post partum.

Secondary outcome

- the amount of remaining microbes in breast milk
- b. the amounts and types of HMOs in breast milk
- c. the amount of butyrate in breast milk.

Study description

Background summary

Rationale

The gut microbiome plays a key role in a healthy immune development of infants, including the prevention of allergies. During the prenatal and postnatal period the intestinal microbial colonization of the infant is established. Diet strongly influences microbial colonization. Naturally, breast milk is the first type of nutrition encountered by infants. However, there are conflicting results on the preventive effect of breast feeding on allergy development in the infant, although most studies found a protective effect.

The following components in breast milk are of specific interest for allergy prevention, based on their influence on the gut microbiome:

1. human milk oligosaccharides (HMOs), because HMOs serve as a prebiotic substrate for the infant's gut bacteria, inducing a beneficial bifidogenic composition
2. butyrate, a short chain fatty acid and metabolite of microbial fermentation
3. the microbial content in breast milk, acting like natural probiotics and interacting with the microbiome of the infant's gut.

Although it is known that diet influences the composition of breast milk, only few studies have focused on this topic. It is unknown if HMOs, butyrate or the microbial composition of breast milk, in other words the synbiotic components of breast milk, can be modified by the mother's diet, e.g. by dietary fiber or the microbial content. Dietary fiber is crucial for a healthy gut microbiome and food-derived microbes are of interest because the consumption of food-derived microbes varies considerably, between 10^5 and 10^{11} microbes (or 10.7 - 10.11 lactobacillae) per day in Dutch adults.

We hypothesize that the synbiotic composition of the diet of the mother is reflected in the synbiotic composition of breast milk and supports the prevention of allergic disease in the infant. In this process, the microbiome of the mother and the infant play a role.

It was shown that bacteria from probiotic supplements (lactobacillus and bifido bacteria) in breast feeding mothers could be found in breast milk and significantly increased the lactobacillus and bifido bacteria in breast milk. No differences were found between colostrum and mature milk with regard to the amount of lactobacillus and bifido bacteria. In our nutrition lactobacillae are the major source of microbial intake.

Therefore, the primary aim of the Synbio-breast study is to study the influence of the amount of lactobacillae in the diet of the mother on the amount of lactobacillae in mature breast milk (4 weeks post partum).

The primary outcome measure is the amount of lactobacillae/ml in mature breast milk

(logCFU), 4 weeks post partum.

The secondary aims are to study the influence of the diet of the mother , specifically dietary fiber and/or the total microbial composition, 3 days and 4 weeks post partum, on secondary outcome measures:

- a. the amount and types of remaining microbes in breast milk
- b. the amounts and types of HMOs in breast milk
- c. the amount of butyrate in breast milk

Study objective

The synbiotic composition of the diet of the mother is reflected in the synbiotic composition of breast milk and sustains the prevention or promotion of the development of allergic disease in the infant.

Study design

Primary outcome, 4 weeks post partum:

Amount of lactobacillae/ml in mature breast milk (logCFU), 4 weeks post partum, measured by IS-pro or 16S sequencing

Secondary outcomes, 3 days and 4 weeks post partum:

- amount of remaining microbes in breast milk, by IS-pro or 16S sequencing, as well as conventional plating
- the amounts and types of HMOs in breast milk by CGE-LIF.
- the amount of butyrate in breast milk.by gas chromatography.

Intervention

none

Contacts

Public

OLVG

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Scientific

OLVG

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Eligibility criteria

Inclusion criteria

- Uncomplicated pregnancy
- Delivery at OLVG out clinic or clinic department or at home
- Atopic (n = 65) and non-atopic (n = 10)
- BMI between 20-35 kg/m² before pregnancy.
- Vaginal delivery
- Intention to breastfeed exclusively for at least 1 months
- Ability to speak and write in Dutch

Exclusion criteria

- Birth before 37 weeks of gestation
- Cesarean section,
- Small for gestational age (P98)
- Supplementary bottle feeding after birth (except for 1 single bottle feeding)
- Antibiotic use within 6 months before study entry or during study
- Probiotic-containing supplement use within 4 weeks before study entry or during study
- Serious concomitant (gastrointestinal) disease
- Fecal transplantation.
- Maternal diabetes during pregnancy
- Moderate to severe atopic dermatitis
- Not able to speak and write in Dutch properly.

Study design

Design

Study type: Observational non invasive
Intervention model: Other
Allocation: Non controlled trial

Control: N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-03-2018
Enrollment:	75
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion	
Date:	04-01-2021
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	NL9168
Other	ACWO OLVG : WO17.186

Study results