Variations in composition of breast milk between different ethnic groups and the association with maternal nutrition and offspring health

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This study aims to investigate the effect of maternal diet and ethnicity on breast milk composition.In addition, we look at possible differences in the intestinal flora and the health of the infant based on the composition of the breast milk and...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Postpartum and puerperal disorders
Study type	Observational non invasive

Summary

ID

NL-OMON55936

Source
ToetsingOnline

Brief title
The MELK study

Condition

- Postpartum and puerperal disorders

Synonym
Breast milk composition

Research involving
Human

Sponsors and support

Primary sponsor: Wageningen Universiteit

Source(s) of monetary or material Support: Ausnutria B.V.,industry: Ausnutria B.V.

Intervention

Keyword: Breast milk, Ethnicity, Infant health, Maternal diet

Outcome measures

Primary outcome

- Breast milk composition: analysis of lipids, proteins, enzymes, immuno

proteins, hormones, amino-acids and carbohydrates

- Maternal diet

Secondary outcome

- Infant gastrointestinal (GI) health

- Infant development

- Infant gut microbiota composition

- Maternal nutritional status

Study description

Background summary

Breast milk naturally provides the infant with the best possible nutrition and it plays an important role in priming the immune system, colonizing the gastrointestinal (GI) tract and protecting against diseases later in life. The composition of breast milk largely varies between women as it changed according to several factors, such as time of the day and time postpartum. The role of maternal diet has been studied several times before, however due to limitations in study design and execution, no conclusions can currently be made on the role of maternal diet and several breast milk components. This information will be of importance in the development of nutritional guidelines aiming to optimize nutrition for both, mothers and infants. Next to that, some women cannot breastfeed their children until the recommended age of 6 month. Infant formula is an important alternative to breast milk for those mothers who cannot breastfeed their children. Therefore, it is of special importance for infant formulas to mimic the natural composition of breast milk as closely as possible

and thus to understand the determinants of breast milk composition.

Study objective

This study aims to investigate the effect of maternal diet and ethnicity on breast milk composition.

In addition, we look at possible differences in the intestinal flora and the health of the infant based on the composition of the breast milk and other characteristics of the mother.

Study design

In this cross-sectional study, data will be collected during 5 study days spread over a 4 week period.
During the first study day, participants will complete a short questionnaire on general characteristics and one food record.
On the second study day, mothers will collect the first breast milk sample and fill in the second food record throughout the day, ending with the second breast milk sample collection the following day. In addition, participants will also be asked to collect a 24-hr urine sample, to assess urinary recovery markers.
On the 3rd study day, mothers will collect 20 ml of pooled breast milk during their morning feed (between 6:00 and 8:00). Mothers will also collect faecal samples of their infants, the sample collection can be planned in on a day of choice of the mothers, but should be completed by the time the researcher is doing the home visit and sample collection (study day 3). The stool sample will be labelled and stored in the household freezer. All other biological samples will be stored in the household fridge and picked up by a research staff on the 3rd study day. During the home visit on study day 3, the researcher will also measure the weight and height of both, mothers and infants.
On the 4th study day, mothers will complete brief questionnaires on general infant characteristics and infant GI health, and complete the third food record.
The 5th study day will be a weekend day, during which mothers will fill in a questionnaire assessing infant development, and complete the fourth and final food record. Together the four food records will enable to estimate the habitual dietary intake of the mothers.

Study burden and risks

No risk is expected for participants participation in this study. The measurements will be home-based and the different questionnaires and sampling procedures were spread out over several study days, to lower the burden on the participants. While there are no direct benefits for the mothers, they still get the opportunity to learn more about their infant and the impact nutrition

can have on breast milk composition and ultimately infant health.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Inclusion criteria

•Aged >18 years
•Having a pre-pregnancy BMI between 18.5 and 24.9 kg/m2
•>6 months pregnant at time of enrollment
•Able to provide a breast milk sample between the 4th and 8th week postpartum
•Planning to exclusively breastfeed until at least 3 months postpartum (this will not include any formula given due to medical reasons within the first week after delivery)
•Fulfilling the criteria of belonging to one of the three ethnicities of interest (see 8.1.1)
•Written informed consent obtained

And her infant was:

• Delivered at full term, at 38 (starting at 37+1) -41 weeks
• Delivered apparently healthy (no diagnosed (chronic) illness)
• Delivered with a birthweight of at least 2,5 kg
• Delivered through vaginal delivery
• Not receiving antibiotics

Exclusion criteria

Mothers cannot participate if they:
• Are expecting twins
• Cannot breastfeed their newborn
• Are currently deviating from their usual dietary pattern (following a diet aimed to lose weight)
•Are experiencing symptoms of (chronic) conditions that might affect nutrient absorption (e.g. Crohn's disease, Irritable Bowel Syndrome)
•Are diagnosed with a gastrointestinal disorder
• Are unable to read and understand the Dutch or English language

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	13-07-2022
Enrollment:	120
Type:	Actual

Ethics review

Approved WMO

Date:	17-03-2022
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	12-10-2023
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	14-03-2024
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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
ISRCTN	ISRCTN35735283
CCMO	NL79447.091.21