ISRCTN35735283 https://doi.org/10.1186/ISRCTN35735283

Understanding the impact of maternal diet and ethnicity on the composition of breast milk

Submission date 03/06/2022	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 10/06/2022	**Overall study status** Completed	
Last Edited 19/02/2025	**Condition category** Digestive System	

Plain English summary of protocol

Background and study aims
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 changes 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, previous studies have indicated a possible influence of maternal ethnicity on breast milk composition. However, these studies did not account for differences in diet between ethnicities, and often standardized protocols were lacking. Information on the role of ethnicity on breast milk composition will help in establishing if there is a need for more research to support more tailored advise.
This study aims to investigate the association of maternal diet and breast milk composition, as well as the association of maternal ethnicity and breast milk composition. A secondary outcome studied will be infant health.

Who can participate?
Pregnant women aged at least 18 years with pre-pregnancy BMI between 18.5 and 24.9 kg/m², over 6 months pregnant at time of enrollment, and 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)

What does the study involve?
The study lasts 4 weeks in which we ask participants on 5 days to complete questionnaires and /or collect breast milk, urine and/or stools. The study days will be planned in consultation with the participants. We expect all measurements in this study to take a total of 3 hours.

We do the following investigations and measurements:
Participants complete a number of questionnaires. The questions are about:
1. demographic data (age, work, education level, etc.), medication use, lifestyle (sleep, stress,

diet, exercise/activities) and children;
2. less frequently eaten foods;
3. the pregnancy, delivery and health of the baby and the baby's nutrition;
4. the baby's gastrointestinal health;
5. the baby's development;
These questionnaires provide information about factors that influence the composition of breast milk. Some questionnaires are longer than others, the shortest takes about 5 minutes to complete and the longest about 45 minutes.

• Participants fill in a food diary 4 times; We will use this information to see if there is a connection between the diet and the composition of breast milk.
• Participants collect breast milk twice; the milk is used to measure the nutrients in the breast milk.
• Participants collect a stool sample from the baby's diaper; The stool is used to see which bacteria are present in the stool.
• Participants collect urine for 24 hours; We will determine a number of nutrients in the urine.
• During the home visit, we measure the height and weight of mothers and their babies and collect the collected samples.
• Finally, we ask participants for permission to request information about the child's growth from the child health center. This data will be used to better understand the relationship between breast milk composition, growth, health and development. If participants do not want us to contact the agency, they can choose not to give your consent, or they can choose not to give consent but to share the information with us themselves during the researcher's visit.

What are the possible benefits and risks of participating?
We do not expect any side effects or complications from participating in the study. Participants fill in a number of questionnaires and collect breast milk, urine and feces. Participants could experience the collection of urine as an extra burden. For example, participants may find it difficult to go outside because they have to collect all urine on the day in question. Participants may also find it inconvenient to keep the urine in the refrigerator and the stool sample in the freezer. In addition, filling in the questionnaires and the visit of the researcher takes time. This may affect their daily habits on the respective study days.
Participants will not directly benefit from participating in this study. But with participation they help the researchers to gain more insight into the composition of breast milk; they help the researchers to gain more insight into factors that can influence the composition of breast milk; they help to set up nutritional advice for women who are breastfeeding.

Where is the study run from?
Wageningen University (Netherlands)

When is the study starting and how long is it expected to run for?
January 2021 to February 2025

Who is funding the study?
Ausnutria B.V. (Netherlands)

Who is the main contact?
Prof. Edith Feskens, edith.feskens@wur.nl

Study website
https://www.wur.nl/en/value-creation-cooperation/nutritional-research/wanted-participants/the-melk-study-nutrition-ethnicity-and-breast-milk-composition.htm

Contact information

Type(s)
Principal Investigator

Contact name
Prof Edith Feskens

ORCID ID
http://orcid.org/0000-0001-5819-2488

Contact details
Helix, Stippeneng 4
Wageningen
Netherlands
6708 WE
+31 317480100
edith.feskens@wur.nl

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
NL79447.091.21

Study information

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

Acronym
The MELK study

Study objectives
1. To explore associations between maternal diet and breast milk composition as well as between maternal ethnicity and breast milk composition.
2. To assess potential associations between breast milk composition and selected aspects of infant health.

Ethics approval required

Old ethics approval format

Ethics approval(s)
Approved 17/03/2022, Medical ethical reviewing committee METC Oost-Nederland (Philips van Leydenlaan 25 (route 348), Netherlands; +31 24 361 31 54; METCoost-en-CMO@radboudumc.nl), ref: 2021-13284

Study design
Observational single centre cross-sectional cohort study

Primary study design
Observational

Secondary study design
Cross sectional study

Study setting(s)
Home

Study type(s)
Other

Participant information sheet
See additional files (in Dutch and English)

Health condition(s) or problem(s) studied
Breast milk composition and infant GI health

Interventions
Participants will fill in questionnaires on demographics, lifestyle, socio-economic status, medication, sleep, stress, physical activity, children, pregnancy, birth, health of the child, GI health of the child and infant development. Besides that, maternal diet will be assessed through food records (4 records over 4 weeks), and a 24h urine collection will be performed to assess dietary intake of nitrogen, potassium and sodium. Lastly, mothers will be asked to provide 2 breast milk samples during 2 consecutive days which will be analyzed on its composition, as well as a stool sample of the infant for gut microbiota analysis.

Intervention Type
Other

Primary outcome measure
Breast milk is collected in the morning of study days 2 and 3, by means of a manual pump. Breast milk composition will be analyzed by Gas chromatography, DUMAS and High-performance liquid chromatography.

Secondary outcome measures
1. Infant GI health, assessed by modified version of the IGSQ questionnaire on study day 4
2. Infant gut microbiota, measured by 16S rRNA gene amplicon sequencing of infant stool sample, taken on study day 2
3. Infant development, measured by Ages and Stages Questionnaire (ASQ) on study day 5

Overall study start date
01/01/2021

Completion date
28/02/2025

Eligibility

Key inclusion criteria
Current inclusion criteria as of 21/12/2023:
Mothers:
1. Aged >18 years
2. Having a pre-pregnancy BMI between 18.5 and 24.9 kg/m²
3. >6 months pregnant at time of enrollment
4. Able to provide a breast milk sample between the 4th and 8th week postpartum
5. 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)
6. Fulfilling the criteria of belonging to one of the three ethnicities of interest (see Snijder, M.B., et al., Cohort profile: the Healthy Life in an Urban Setting (HELIUS) study in Amsterdam, The Netherlands. BMJ Open, 2017. 7(12): p. e017873.)
7. Written informed consent obtained

Infants:
8. Delivered at full term (at 38-41 weeks)
9. Delivered apparently healthy (no diagnosed (chronic) illness)
10. Delivered with a birthweight of at least 2.5 kg
11. Delivered through vaginal delivery
12. Not receiving antibiotics

———

Previous inclusion criteria:
1. Aged >18 years
2. Having a pre-pregnancy BMI between 18.5 and 24.9 kg/m²
3. >6 months pregnant at time of enrollment
4. Able to provide a breast milk sample between the 4th and 8th week postpartum
5. 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)
6. Fulfilling the criteria of belonging to one of the three ethnicities of interest (see Snijder, M.B., et al., Cohort profile: the Healthy Life in an Urban Setting (HELIUS) study in Amsterdam, The Netherlands. BMJ Open, 2017. 7(12): p. e017873.)
7. Written informed consent obtained
And her infant was:
8. Delivered at full term (at 39-41 weeks)
9. Delivered apparently healthy (no diagnosed (chronic) illness)
10. Delivered with a birthweight of at least 2.5 kg
11.Delivered through vaginal delivery
12. Not receiving antibiotics

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
120, 40 per ethnicity

Total final enrolment
120

Key exclusion criteria
Current exclusion criteria as of 21/12/2023:
Mothers will be excluded from participation if they:
1. Are expecting/gave birth to twins
2. Cannot breastfeed their newborn
3. Are already breastfeeding another infant
4. Are currently deviating from their usual dietary pattern (following a diet aimed to lose weight)
5. Are diagnosed with a gastrointestinal disorder
6. Are unable to read and understand the Dutch or English language

———

Previous exclusion criteria:
1. Expecting/gave birth to twins
2. Cannot breastfeed their newborn
3. Currently deviating from their usual dietary pattern (following a diet aimed to lose weight)
4. Are unable to read and understand the Dutch language

Date of first enrolment
01/07/2022

Date of final enrolment
31/12/2024

Locations

Countries of recruitment
Netherlands

Study participating centre
Wageningen University
Helix, Stippeneng 4

Wageningen
Netherlands
6708 WE

Sponsor information

Organisation
Wageningen University & Research

Sponsor details
Stippeneng 4
Wageningen
Netherlands
6708 WE
+31 317480100
office.hn@wur.nl

Sponsor type
University/education

Website
https://www.wur.nl/

ROR
https://ror.org/04qw24q55

Funder(s)

Funder type
Industry

Funder Name
Ausnutria B.V.

Results and Publications

Publication and dissemination plan
Main results will be published in peer-reviewed journals and presented at scientific conferences or symposia

Intention to publish date
28/02/2025

Individual participant data (IPD) sharing plan

The data-sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	in Dutch version 4	09/03/2022	10/06/2022	No	Yes
Participant information sheet	in English version 5	19/06/2023	21/12/2023	No	Yes
Results article		18/02/2025	19/02/2025	Yes	No