A longitudinal prospective, observational, cohort study in lactating mothers and their newborns to further unravel the complexity of human milk

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The objective of this study is to further unravel the complexity of human milk and its variations over lactation stages and between individuals.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON53220

Source
ToetsingOnline

Brief title
White Gold

Condition

- Other condition

Synonym
Not applicable

Health condition

studie met gezonde vrijwilligers

Research involving
Human

Sponsors and support

Primary sponsor: Nutricia Research
Source(s) of monetary or material Support: Nutricia Research B.V.

Intervention

Keyword: Breastfeeding, Human milk, Research, White Gold

Outcome measures

Primary outcome

Outcome parameters:

Examples of the exploratory outcome parameters in this study are the following

human milk outcome parameters at Day 3 and at Week 1.5, 4, 10, 26, 52, and 104:

* Proteins

* Amino acids

* Lipids

* Fatty acids

The following exploratory faecal outcome parameter at Day 3 and at Week 1.5, 4,

10, 26, 52, and 104 will be analysed if sufficient faecal samples are collected:

* Infant*s faecal microbiome composition

Secondary outcome

Not applicable.

Study description

Background summary

The current observational cohort study design will make it possible to explore human milk composition and functionality and to explore human milk composition across different lactation stages, between different human milk groups, and in relation to maternal, perinatal, infant, and sample characteristics as well as to the microbiota of the infant.
The proposed timepoints at which human milk samples (and optionally faecal samples) will be collected cover all different lactation stages:
* Colostrum (first [1-5] days postpartum)
* Transitional milk (1.5 weeks postpartum; preferred time window: 6-15 days postpartum)
* Early to mature milk (4 weeks postpartum; preferred time window: 3-8 weeks postpartum)
* Mature milk before weaning (10 weeks postpartum; preferred time window: 9-12 weeks postpartum)
* Mature milk after weaning (26±2 weeks postpartum)
Furthermore, the following additional timepoints are included because the majority of current research lack data from the period after 6 months postpartum:
* Mature milk (52±2 weeks postpartum)
* Mature milk (104±2 weeks postpartum)

The current study will be conducted in The Netherlands, in an area in proximity of Danone Nutricia Research Utrecht. The collected human milk samples and infants* faecal samples will be shipped to and processed by Nutricia Research laboratories in Utrecht, The Netherlands.

Study objective

The objective of this study is to further unravel the complexity of human milk and its variations over lactation stages and between individuals.

Study design

A longitudinal prospective, observational, single-centre, exploratory, cohort study

Study burden and risks

Subjects will be asked to complete an initial digital questionnaire after signing informed consent. Then, at 7 time points spread over 2 years, subjects will be asked to complete a digital questionnaire, collect breast milk sample(s) and an optional fecal sample from the infant. The lab samples will be collected from the subject's home by a courier. At an end of the study, the subject will be asked to complete a final evaluation.
The burden for participants in this study is considered small. Subject participation contributes to gaining more knowledge about the composition and

functionality of breast milk and improving nutrition for infants and young children; this outweighs the low burden.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Babies and toddlers (28 days-23 months)
Newborns

Inclusion criteria

1. Pregnant women in the third trimester of pregnancy (>=28 weeks) who have the intention to provide breastfeeding for at least 6 months post-partum
2. Age >= 18 years
3. Willingness to provide residual human milk
4. Located in proximity of NCRU
5. Dutch speaking and reading
6. Freezer -18°C available
7. Having mobile phone, tablet, or computer available

8. Signed informed consent from subject (pregnant woman)
9. Signed informed consent from the other parent and/or legally acceptable representative of the unborn baby(s), aged >= 18 years.

Exclusion criteria

1. Pregnant women known positive for human immunodeficiency virus (HIV), hepatitis B (HBV) or hepatitis C (HCV) (self-reported). 2. Multiple pregnancy (more than 2). 3. Incapability of subjects to comply with study protocol as per the judgment of the study staff (e.g. fluency in local language, access to laptop/smartphone devices and internet connection required for data collection). 4. Women (and their unborn baby(s)) with current or intended participation in any other clinical study involving investigational or marketed products. 5. Employees and/or children/family members or relatives of employees of Nutricia Research or the participating site. After enrolment the following continuation criteria will lead to discontinuation of the study. 1. Still birth. 2. Newborn having any congenital abnormality, chromosomal disorder or severe disease that would prevent the infant from breastfeeding and growing normally based on the opinion of a health care professional and/or study physician. 3. No donation of any milk sample within the first 8 weeks postpartum (timepoints week 1, week 1.5, and week 4).

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	13-02-2024
Enrollment:	120
Type:	Actual

Ethics review

Approved WMO Date:	12-07-2023
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

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
CCMO	NL84310.056.23