Comparison of human milk extracellular vesicles in allergic and non-allergic mothers

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To define differences in the molecular composition of human milk extracellular vesicles between allergic and non-allergic mothers. Additionally, other differences in human milk composition will be analyzed (cellularity, nutrient content,...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Allergic conditions
Study type	Observational non invasive

Summary

ID

NL-OMON40212

Source
ToetsingOnline

Brief title
ACCESS

Condition

- Allergic conditions

Synonym
allergies, hooikoorts

Research involving
Human

Sponsors and support

Primary sponsor: Martini Ziekenhuis
Source(s) of monetary or material Support: Nutricia Research

Intervention

Keyword: atopy (development), extracellular vesicles, human milk

Outcome measures

Primary outcome

Comparison of the (potential) differences in extracellular vesicle content and function between allergic and non-allergic mothers. In this exploratory study many state of the art techniques will be used, including multiplex assays (targeted protein assays), proteomics (untargeted protein analysis), western blot, high resolution flow cytometry, RNA analysis. The main endpoint of the study would be the identification of a difference in human milk extracellular vesicle content between allergic and non-allergic mothers with the potential to be developed into a biomarker for maternal allergy status, for predicting atopy development in the offspring, and/or for assessing the efficiency of anti-allergic therapies to preventatopy development in the offspring.

Secondary outcome

Not applicable

Study description

Background summary

It has been demonstrated that the maternal immune status influences the composition of human milk and affects the onset of chronic immune-related diseases, such as allergies, later on in the infant*s life. How human milk actually influences the development of the infant*s immune system and chronic diseases is not known. Human milk contains various immune-modulatory components and has recently been shown to contain immune-modulatory extracellular vesicles. These are nano-sized membrane vesicles of which the secretion, cargo composition (including proteins and (micro)RNAs), and targeting is tightly

regulated. This has led to the hypothesis that extracellular vesicles are tailor-made messengers for specific intercellular communication. Therefore, human milk-derived extracellular vesicles could play a role in the maternal imprinting and programming of the infant*s immune system via the gastrointestinal tract. It has been described that children of allergic mothers have a higher risk of developing allergic conditions. This exploratory study will investigate the potential role of human milk extracellular vesicles in this process by comparing the molecular composition of vesicles in milk from allergic and non-allergic mothers. If differences are found, these can be used as predictive/prognostic biomarkers and as potential targets for future interventions. Since extracellular vesicles physically combine physiologically relevant biological markers in a single vesicle, we expect that extracellular vesicle-based biomarkers are a valuable extension of currently available biomarkers.

Study objective

To define differences in the molecular composition of human milk extracellular vesicles between allergic and non-allergic mothers. Additionally, other differences in human milk composition will be analyzed (cellularity, nutrient content, immunological and inflammatory markers) and outcomes will be linked to atopy in the infants at 1 year of age.

Study design

exploratory observational study

Study burden and risks

There are no specific risks associated with participation in this observational study. Obviously, due to the observational nature of this study, there is no potential health benefit associated with participation either. The light burden of the study procedures are balanced by the psycho-emotional benefit of contributing to a study to increase the scientific knowledge on the relationship between maternal allergy, human milk composition and atopy/allergy development in the child.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Age 18 years or above
- The infant that is subject of breastfeeding was born term (gestational age 37-42 weeks) via vaginal delivery
- Breastfeeding started from birth onwards;Inclusion criteria specific for the allergic donor group:
- Established perennial or seasonal allergies against common inhalant or environmental allergens (e.g. house dust mite, pet allergens, pollen etc.)
- Total serum IgE * 50 kU/L OR specific IgE detected by positive Phadiatop assay;Inclusion criteria specific for the non-allergic donor group:
- No history and symptoms of allergy
- Total serum IgE: <50kU/L and negative Phadiatop analysis at screening.
- Absence of any atopy related condition, including diagnosed allergic asthma (defined as using any medication for asthma treatment) and diagnosed atopic dermatitis (defined as using any medication for atopic dermatitis treatment)

Exclusion criteria

- Use of systemic immunosuppressive or immunomodulatory medication, e.g. systemic corticosteroids (including use for treatment of severe asthma or atopic dermatitis),

immunomodulatory biologicals, chemotherapeutics, use of NSAIDs in the week before inclusion / milk donation.
- Altered immune function (see protocol for list)

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-10-2014
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO

Date:	21-07-2014
Application type:	First submission
Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)

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	NL47426.099.14