Protecting against Respiratory tract Infections through human Milk Analysis.

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Primary objective:1. To identify the components in human milk (e.g. nutrients, oligosaccharides, fatty acids and (pathogen specific) immunoglobulins) that have a protective effect against respiratory tract infections during the first year of life....

Ethical review	Not approved
Status	Will not start
Health condition type	Allergic conditions
Study type	Observational invasive

Summary

ID

NL-OMON48053

Source
ToetsingOnline

Brief title
PRIMA

Condition

- Allergic conditions
- Hepatobiliary neoplasms malignant and unspecified

Synonym
pneumonia, Respiratory tract infection

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Dit onderzoek wordt gefinancierd middels een grant van Nutricia Research BV. ,Nutricia

Intervention

Keyword: Antibodies, Human milk, Oligosaccharides, Respiratory tract infections

Outcome measures

Primary outcome

The amount of medically attended respiratory tract infections during the first year of life.

Secondary outcome

1. The amount of medically attended respiratory tract infections for every quarter of a year during the first year of life.

2. The amount of prescribed antibiotic treatments for respiratory tract infections during the first year of life.

3. The total amount of respiratory tract infection periods during every quarter of a year for the first year of life.

4. Food allergies diagnosed by a physician during the first year of life.

5. Inhalation allergies diagnosed by a physician during the first year of life.

6. Eczema diagnosed by a physician during the first year of life.

Study description

Background summary

We aim to identify mechanisms by which breast feeding prevents respiratory tract infections. A healthy birth cohort (n=1000) will be set-up and studied during the first year of life. Human milk will be collected repeatedly and analysed to provide insights into the protective capacity of human milk components against (respiratory tract) infections and allergies.
A subgroup will be further analyzed to obtain insight in transfer of maternal immunity to the child. By collecting additional cord blood, amniotic fluid and

maternal blood samples, we will analyze the transfer of maternal immunity.

Study objective

Primary objective:
1. To identify the components in human milk (e.g. nutrients, oligosaccharides, fatty acids and (pathogen specific) immunoglobulins) that have a protective effect against respiratory tract infections during the first year of life.

Secondary objective:
2. The underlying mechanism of the components in human milk that offer protection from respiratory tract infections during the first year of life.
3. To identify the components in human milk (e.g. nutrients, oligosaccharides, fatty acids and (pathogen specific) immunoglobulins) that have offer from developing allergies during the first year of life and to identify the underlying mechanism of these components.
4. To study the alterations in human milk composition at various time points.
5. To gain insight in the transfer of maternal immunity to their child via human milk, amniotic fluid and the placenta.

Study design

The study is designed as a prospective observational cohort study, including 1000 healthy mother-child pairs. Directly after birth we will collect data from all children enrolled through a questionnaire that is send to parents every 2 weeks. The questionnaires will be used to collect data about episodes of (respiratory tract) infections and already developed allergies during the first year of age.
Meanwhile, we will collect human milk samples at four time points: within 1 week postpartum and after 1 month, 3 months and 6 months postpartum. By collecting human milk at these time points, we expect to collect samples from all relevant time-dependent types of human milk. The human milk samples will be stored until analysis at the biobank facility of the UMC Utrecht.
After analysis of human milk composition is performed and clinical data collected, we will compare the two database in order to find beneficial profiles of human milk components.

Additionally we will also collect additional samples to research what the influence of breastfeeding is on immune development compared to other routes that are enrolled in the transfer of maternal immunity to the neonate. This we will de in a subgroup of 20 mother-child dyads. The samples that we will collect are cord blood samples, a maternal blood sample and an amniotic fluid sample. Jacobino et al. showed that antibodies retrieved form human amniotic fluid protected mice pups against RSV-infections (JACOBINO2016). Very little is known about the protective value antibody titers in cord blood. Active placental transport of maternal antibodies to the neonatal blood has been

described, but little is known about the effectiveness of these antibodies (KOHLER1966). To obtain more insight in the effect of the antibodies that are being transferred by breastfeeding, we will compare the effect of breastfeeding to the antibodies in cord blood and amniotic fluid. We will also collected saliva samples in the children enrolled n this subgroup at 1 week, 1, 3, 6, and 12 months postpartum. Saliva samples will be used to study immune development in children.

Study burden and risks

Only parents will be burdened by participating in this study. Parents will be visited by researchers four times maximum. Children will not be affected by the collection of human milk samples, since they are a rather small fraction of the total amount of breastfeeding.
Apart from human milk collection, parents will have to fill in questionnaires every 2 weeks that will take 1-2 minutes to complete. Additionally parents will have to fill in three more extensive questionnaires that will take about 300 minutes each to complete (i.e. baseline, midterm and end-of-study questionnaires). In total, the maximal estimated amount of hours will be 5-6 hours for each child.
There is a minimal risk associated with the venipuncture. Although considered safe, rarely phlebitis, extravasation of blood, bruising and hematoma forming following venipuncture have been reported. However, since complications form venipunctures and expressing milk are rare, and we will decrease the risk of a data breach as best as we can with our DMP, we asses these risks for mothers acceptable. No risk is associated with the collection of amniotic fluid or saliva.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Children (2-11 years)
Elderly (65 years and older)

Inclusion criteria

All healthy childen (and their parents) born at a minimal gestational age of 32 weeks.

Exclusion criteria

Exclusion criteria concerning the child:
- Congenital heart defect.
- Congenital lung disorder or other severe organ dysfunction.
- (extreme) prematurtity (<32 weeks GA)., Concerning the parents:
- Congenital or acquired immunodeficiency (except for allergies, eczema and hay fever).
- Presence of a medical condition or use of medication in mothers that contraindicates breastfeeding.
- Insufficient control of the Dutch Language (>B1 CEFR level).

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled

Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	1000
Type:	Anticipated

Ethics review

Not approved

Date:	19-02-2020
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL69145.041.19