Protecting against Respiratory tract Infections through human Milk Analysis.

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Human milk contains (a combination of) components that might protect infants from (respiratory tract) infections and allergic diseases.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON23847

Bron
Nationaal Trial Register

Verkorte titel
PRIMA

Aandoening

(respiratory) infections and allergic diseases.

Ondersteuning

Primaire sponsor: Nutricia reserach bv.
Overige ondersteuning: Nutricia research B.V., WKZ research fund-Nutricia call 2020, the Dutch government as part of the Regiodeal Food Valley

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Parent-reported medically attended respiratory tract infection during the first year of life

Toelichting onderzoek

Achtergrond van het onderzoek

Background of the study:
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.

Objective of the study:
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.

Doel van het onderzoek

Human milk contains (a combination of) components that might protect infants from (respiratory tract) infections and allergic diseases.

Onderzoeksopzet

Inclusion at the first week postpartum, human milk sample collection at 1 week and 1, 3 and 6 months postpartum. Two-weekly questionnaires send to participants until children reach the age of one.

Onderzoeksproduct en/of interventie

None.

Contactpersonen

Publiek

UMC Utrecht
Arthur van Stigt

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen

(Inclusiecriteria)

- All mother-child dyads that live in a proximity to Utrecht (because of logistical issues) and/or gave birth at the WKZ.
- Parents should have the intention to continue breastfeeding until at least 3 months postpartum

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Concerning the child:
(inborn) severe cardiac or pulmonary disorders or other severe organ diseases
- Extreme prematurity (defined as GA<32 weeks).
- Concerning parents:
- Acquired or innate immune deficiencies (excluding asthma, eczema and allergies).
- The (lactating) mother receives medication or has a physical condition which forms a contraindication for breastfeeding.
- Insufficient control of the Dutch language (i.e. at least B1 level).

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-11-2020
Aantal proefpersonen:	1000
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Toelichting
n.a.

Ethische beoordeling

Positief advies

Datum:	18-11-2020
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 51989
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL9056
CCMO	NL74946.041.20
OMON	NL-OMON51989

Resultaten

Samenvatting resultaten
n.a.