Study on the effects of a growing-up milk (GUM)on infections in healthy children

Gepubliceerd: 11-09-2014 Laatst bijgewerkt: 13-12-2022

Consumption of the new developed GUM will decrease the incidence of upper respiratory tract infections (URTI) and/or decrease the duration of acute gastrointestinal tract infections (GITI) in Asian toddlers

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON19929

Bron
NTR

Verkorte titel
VIVALDI

Aandoening

Upper respiratory tract infections (URTI)
Gastrointestinal tract infections (GITI)

Ondersteuning

Primaire sponsor: Chinese University of Hong Kong
Overige ondersteuning: FrieslandCampina

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

- Incidence of URTI (Upper respiratory tract infections)

- Duration of GITI (Gastrointestinal tract infections)

Toelichting onderzoek

Achtergrond van het onderzoek

Background

Based on incidence figures in various South-East Asian countries it is clear that upper respiratory infections and infection-induced diarrhoea are major health issues in 1-3 year olds. Morbidity due to respiratory and gastrointestinal infections is very high. Common way of parents on dealing with those diseases is seeking for medical help, but medical treatment is little helpful in many, mostly uncomplicated cases. In most cases, the infant's body has to resolve the infection on its own and a strong immune system is needed for this. It is known that breastfeeding protects against respiratory and infection-induced diarrhoea compared to the current infant and toddler nutrition. In this nutritional intervention trial in healthy Asian toddlers we propose to test the effect of three new GUM compositions compared to a current commercial GUM (GUM REF) on the child's immune system by targeting common respiratory and gut infections.

Hypothesis

Consumption of GUM-A containing active proteins, milk fat and a specific oligosaccharide decreases the incidence of URTI and/or decreases the duration of acute GITI in Asian toddlers (1-3 yrs of age) compared to consumption of reference GUM (GUM-REF). Two derivatives of GUM-A, named GUM-B and GUM-C, are expected to have intermediate outcomes on incidence of URTI and duration of GITI.

Design

A randomized, controlled, double-blind, parallel-group clinical trial with four study arms including 138 children (1-3 years old) per arm. GUM-A, B and C will be compared with GUM REF.

Doel van het onderzoek

Consumption of the new developed GUM will decrease the incidence of upper respiratory tract infections (URTI) and/or decrease the duration of acute gastrointestinal tract infections (GITI) in Asian toddlers

Onderzoeksopzet

Baseline visit: Physical examination, FFQ, collection of nose swab, fecal sample, saliva sample, and start of diary.

Intervention: 6 month, daily drinking of the GUM, 2 glasses of 200 ml

Every 2 months: visit with physical examination
Every URTI/ GITI episode: collection of nasal or fecal sample resp.

Endline visit after 6 months intervention: physical examination, nose swab, fecal sample, saliva sample, and end diary

Onderzoeksproduct en/of interventie

GUM A: containing intact active proteins, milk fat, and a prebiotic

GUM B: containing only intact active proteins

GUM C: containing a prebiotic

GUM REF: commercial available growing up milk

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Apperently healthy

- Between 1 and 2.5 years of age at inclusion, with a preference of 1-1.5 years

- Boys and Girls of Chinese origin, living in Hong Kong

- Able and willing to drink 400 ml milk per day (2 servings of 200 ml each)

- Singned informed consent

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Underweight, wasting, or stunting (according to WHO criteria)

- Clinically significant congenital diseases

- In sick condition within two weeks prior to screening visit

- Receive antibiotics, anti-viral drugs, montelukast, laxatives, or anti-diarrhoeal drug within 1 month before intervention starts

- Any breastfeeding within last 2 months before intervention starts

- Suspected tuberculosis by clinical or radiological examination or from history of contact with index patient with confirmed tuberculosis

- Cow's milk allergy

- History of severe allergic diseases (mild eczema of mild asthma is NOT excluded if unrelated to cow's milk allergy)

- Usage of systemic immunosuppressive drugs within 3 months prior to screening visit (incidental use of topical, inhalational and intranasal corticosteroids are allowed)

- Received rotavaccin ever

- Received influenze vaccin within 12 months prior to recruitment

- History of lactose intolerance

- Siblings of already recruited children that are living in the same household with the exception of twins that can be allocated to the same group

- Participation in another clinical trial at the same time or within 2 months prior to intervention starts

- Children from mothers or caregivers whoare illiterate or unable to read and write Chinese

- Premature (<37 weeks of gestation) at birth

- No full committment of parents to omit dairy drinks from the child's diet during the study and replace these by the supplied growing up milk

4-apr-2016: One criterion on siblings changed into “Siblings of already recruited children that are living in the same household with the exception of twins that can be allocated to the same group. Recruitment of younger sibling of a subject (older sibling) from the same household is allowed provided that the subject (older sibling) has ended his/her participation in this study and the family returned unused GUM to the study site. The allocation of treatment group for the younger sibling will be independent of that for the older sibling.”

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-01-2015
Aantal proefpersonen:	464
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	11-09-2014
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL4627
NTR-old	NTR4779
Ander register	NA : P511761

Resultaten

Samenvatting resultaten
NA