

SAMSAM

Gepubliceerd: 28-10-2021 Laatste bijgewerkt: 15-05-2024

Our hypothesis is that children who become colonized with *Streptococcus pneumoniae* have low levels of PS-specific memory B cells at the time of exposure.

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

Samenvatting

ID

NL-OMON21999

Bron

NTR

Verkorte titel

TBA

Aandoening

Respiratory tract infections

Ondersteuning

Primaire sponsor: Leiden University Medical Center

Overige ondersteuning: Bill & Melinda Gates Foundation

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Assess dynamics of pneumococcal colonisation using daily nasal sampling and the association of this with levels of pre-existing polysaccharide specific memory B cells.

Toelichting onderzoek

Achtergrond van het onderzoek

Respiratory tract infections (RTI) are a major cause of morbidity in young children in high-income countries and the major cause of mortality in developing countries. The aetiology of lower RTI (LRTI) is often polymicrobial, involving well-known viral or bacterial pathogens or combinations of both. LRTI pathogens all originate in the nasopharynx. Usually these bacteria are regular residents of the nasopharynx of asymptomatic individuals and live there together with other presumed harmless commensals, without causing disease. Together they are a complex bacterial community, called the nasopharyngeal (NP) bacterial microbiome. In addition to bacteria, viruses are also found in the nasopharynx during respiratory tract infection and in asymptomatic individuals. These infections are important for transmission, intermediate step to disease and boost immune responses. Such infections are extremely dynamic, but very few studies have been able to characterize them due to the discomfort related to classical sampling methods, such as nasopharyngeal swabs (NPS). We recently validated the use of minimally-invasive nasal sampling methods that can be done at home for the study of host and microbial parameters in adults and children. In this study we will focus on the daily microbial and immunological composition of the nasopharynx during health in relation to symptoms.

Doel van het onderzoek

Our hypothesis is that children who become colonized with *Streptococcus pneumoniae* have low levels of PS-specific memory B cells at the time of exposure.

Onderzoeksopzet

Daily sampling for 28 consecutive days

Contactpersonen

Publiek

LUMC
Dennis Hoving

0715269278

Wetenschappelijk

LUMC
Dennis Hoving

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- a) Child aged 1-5 years of age attending day care, peuterspeelzaal or school at least 2 (half) days a week.
- b) Parents ability and willingness to adhere to protocol-specified procedures, including availability of a freezer at home to store samples. This does not include donation of saliva by parents themselves, which is related to a secondary endpoint.
- c) Written informed consent will be obtained from all legal representatives, for example both parents.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- a) History of respiratory tract infections requiring hospitalization.
- b) Current use of antibiotics, or antibiotics use in past four weeks.
- c) Use of immune-altering medication (such as steroids, including inhaled corticosteroid).
- d) History of severe concomitant disease (severe congenital heart disease, bronchopulmonary dysplasia, prematurity <32 weeks, cystic fibrosis, sickle cell disease, congenital or acquired immunodeficiency disorders, cardiovascular disease, neuromuscular disorders, oncology patients or major congenital anomalies).

Onderzoeksopzet

Opzet

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

Deelname

Nederland
Status: Werving gestart
(Verwachte) startdatum: 06-09-2021
Aantal proefpersonen: 45
Type: Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies
Datum: 28-10-2021
Soort: Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 52240
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL9846
CCMO	NL77975.058.21
OMON	NL-OMON52240

Resultaten