nasopharyngeal colonization in children and parents

Gepubliceerd: 24-08-2015 Laatst bijgewerkt: 15-05-2024

The current OKIDOKI-4 study is part of an ongoing surveillance program intended to monitor the carriage of Streptococcus pneumoniae (pneumococcus) serotypes through collection of nasopharyngeal swabs in children and their parents. S. pneumoniae is...

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

Samenvatting

ID

NL-OMON25799

Bron
NTR

Verkorte titel
OKIDOKI-4

Aandoening

Pneumococcal carriage
Prevenar
Synflorix
PCV7
PCV10

Ondersteuning

Primaire sponsor: National Institute for Public Health and the Environment
Overige ondersteuning: Ministry of Health, Welfare and Sport

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Total pneumococcal vaccine and non-vaccine serotypes

Toelichting onderzoek

Achtergrond van het onderzoek

Cross-sectional surveillance study on pneumococcal serotypes and other pathogens in nasopharyngeal samples from children and parents performed in the tenth year after introduction of pneumococcal vaccination in The Netherlands in 330 24-month-old children, 330 46-month-old-children and 330 parents of 24-month-old-children

Doel van het onderzoek

The current OKIDOKI-4 study is part of an ongoing surveillance program intended to monitor the carriage of Streptococcus pneumoniae (pneumococcus) serotypes through collection of nasopharyngeal swabs in children and their parents. S. pneumoniae is the leading cause of invasive pneumococcal disease (IPD) like meningitis, sepsis and bacteremic pneumonia as well as of respiratory infections like community acquired pneumonia and otitis media. The highest disease incidence is observed in children below two years of age and in elderly >65 years of age. Diseases caused by S. pneumoniae are preceded by asymptomatic nasopharyngeal acquisition and colonization. Vaccination with a 7-valent pneumococcal vaccine (Prevenar-7, PCV-7) was introduced in the Dutch National Immunization Program (NIP) for children in 2006 and replaced in 2011, by a 10-valent vaccine (PCV-10). PCV vaccination reduced acquisition and density of colonization of vaccine-serotype pneumococci in the nasopharynx of vaccinated children and subsequent transmission to others leading to an indirect protection of the community (herd effect). The vacant niche in the nasopharynx of vaccinated children is however immediately filled by non-vaccine pneumococci and possibly other potential pathogens that may be involved in respiratory or invasive disease.

Surveillance of nasopharyngeal carriage of pneumococci is important to evaluate shifts in circulation of specific serotypes after pneumococcal conjugate vaccine introduction as a measure for vaccine effectiveness and impact. This surveillance information is used to determine whether adjustments in the vaccination program/strategy are needed.

Onderzoeksopzet

children of 24 months of age (and one parent of each child).

children of 46 months of age.

One home visit per child.

Onderzoeksproduct en/of interventie

not applicable

Contactpersonen

Publiek

RIVM
Alienke Wijmenga-Monsuur
Bilthoven 3720 BA
The Netherlands
na

Wetenschappelijk

RIVM
Alienke Wijmenga-Monsuur
Bilthoven 3720 BA
The Netherlands
na

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

•The children have to be of normal health (same health criteria apply as used in well-baby clinics when a child receives a vaccination, e.g. also children with small increases in temperature or cold are seen as children with normal health, fever >38.5°C in the last two days is not considered as normal health)

•The parents have to be willing and able to participate in the trial according to procedure

•The child is 24-months-old or 46-months-old (± 4 weeks)

•The child has been vaccinated according to the Dutch NIP

•Presence of a signed informed consent (the parents/legally representatives have given written informed consent after receiving oral and written information)

•Parents of 24-month-old children are included when their child fulfils the inclusion criteria

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

•Previous vaccinations with PCV using a vaccine and schedule that differs from the Dutch NIP of that age group

•Medical conditions that will severely affect immunological responses to vaccinations or NP carriage rates (certain chromosomal abnormalities or craniofacial abnormalities (like Trisomy 21 or schisis), known or suspected immunodeficiency disease or other medical conditions)

•Coagulation disorder/anticoagulant medication

A parent who meets any of the following criteria will be excluded from participation in this study:

•Medical conditions that will severely affect immunological responses to vaccinations or NP carriage rates (certain chromosomal abnormalities or craniofacial abnormalities (like Trisomy 21 or schisis), known or suspected immunodeficiency disease or other medical conditions)

•Coagulation disorder/anticoagulant medication

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	Niet-gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	18-08-2015
Aantal proefpersonen:	990
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:	24-08-2015
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 42659
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL5296
NTR-old	NTR5405
CCMO	NL53027.094.15
OMON	NL-OMON42659

Resultaten