Nasopharyngeale pneumokokken en meningokokken kolonisatie

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28461

Source
Nationaal Trial Register

Brief title
OKIDOKI-5

Health condition

Pneumococcal carraige and meningococcal carriage

Sponsors and support

Primary sponsor: National Institute for Public Health and the Environment (RIVM)
Source(s) of monetary or material Support: Ministery of Health and Social Affairs ZonMW

Intervention

Outcome measures

Primary outcome

to determine vaccine- and non-vaccine serotype-specific pneumococcal carriage by culture.

Secondary outcome

Secondary; to determine pneumococcal presence, density and multi-serotype carriage analysis using molecular
methods, impact of PCV on presence of other nasopharyngeal respiratory non-pneumococcal bacteria and viruses,
meningococcal carriage by culture and meningococcal carriage, density and co-carriage by molecular methods and to
compare resuits of culture and molecular methods, antibiotic resistance of isolates, the impact of vaccination on the
microbiome and salivary antibodies.

Study description

Background summary

Current study is part of our long-term surveillance intended to monitor changes in serotype specific pneumococcal nasopharyngeal carriage since introduction of pneumococcal vaccination in the NIP in vaccinated children and their unvaccinated parents. In response to the recent increase of invasive meningococcal disease incidence due to meningococcal W, the Minister of Health decided to replace the monovalent meningococcal conjugate vaccine against MenC by the 4-valent conjugate vaccine MenACWY vaccination in spring 2018. The impact of MenACWY vaccination on the vacant niche is currently unknown. Pneumococcal and meningococcal carriage in young children will be monitored in the OKIDOKI-5 study. The study population consists of 330 24-month-old children that have been vaccinated according to the NIP, siblings of the participating children (24-month-old - <6 years of age) and one of the parents/legal guardians of each child. The children only received MenC vaccination not MenACWY. During a home visit saliva and a throat swab are collected of all participants. Of the 24-month old children also a nose swab is taken. The objective is to monitor changes in pneumococcal carriage after pneumococcal vaccination and to determine the best method for detection of meningococcal carriage. Results of the current meningococcal carriage can serve as a baseline for future studies.

Study objective

Current study is part of our long-term surveillance intended to monitor changes in
serotype specific pneumococcal nasopharyngeal carriage since introduction of pneumococcal vaccination in the NIP in vaccinated children and their unvaccinated parents. Streptococcus pneumoniae (pneumococcus) 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. Disease caused by Streptococcus pneumoniae is preceded by asymptomatic nasopharyngeal acquisition and colonization. Neisseria meningitidis, the bacterium that causes meningococcal disease, is an obligate

commensal of humans, which transiently colonizes the mucosa of the upper respiratory tract but only occasionally causing invasive meningococcal disease (IMD), depending on the clonal type and low population immunity to the particular strain. IMD is relatively rare (at present 100-150 cases/year in the Netherlands) but with severe symptoms and with mortality up to 20%, the burden of IMD remains high. Meningococci can be classified into 13 serogroups based on the capsular polysaccharides Chemistry and immunogenicity. Of these 13 serogroups, six are responsible for the vast majority of disease
cases with strains of serogroup B, W and Y dominating in IMD in the Netherlands. The incidence is highest in children under 5 years of age followed by adolescents, young adults and elderly of over 75 years of age. Although cases of IMD are generally rare, the severity of disease and the occurrence of outbreaks strongly support a role for prevention by vaccination. Disease onset is often a-specific but, within hours IMD progresses towards meningitis, sepsis and/or septic shock. 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). In response to the recent increase in MenW IMD incidence, the Minister of Health decided to replace the monovalent meningococcal conjugate vaccine against MenC by the 4-valent
conjugate vaccine MenACWY vaccination in spring 2018. In addition, MenACWY conjugate vaccination will be implemented at the age of 14 years in September 2018. PCV-10 and possibly
also MenACWY vaccine reduce the acquisition and density of vaccine serotypes in the nasopharynx of vaccinated children and subsequent reduces transmission to others leading to an indirect protection of the community (herd effects) thus enhancing the public health effect and costeffectiveness
of this approach. After PCV vaccination the vacant niche in the nasopharynx of
vaccinated children is immediately filled by non-vaccine pneumococci and possibly other potential
pathogens that may be involved in respiratory or invasive disease. The impact of MenACWY vaccination on the vacant niche is currently unknown. Pneumococcal and meningococcal carriage in young children will be monitored in the OKIDOKI-5 study.

Study design

One home visit per child/parent.

Intervention

A transnasal and transoral naopharyngeal swab and two saliva samples will be taken from the participants (parents and older siblings; no transnasal swab).

Contacts

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Eligibility criteria

Inclusion criteria

•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/legal guardians have to be willing and able to participate in the trial according to procedure

•The child is 24-months-old (± 8 weeks) or for older siblings; the child is between 24 month (-4 weeks) and <6 years of age)

•The child has been vaccinated according to the Dutch NIP (including MenC vaccination, not MenACWY vaccination)

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

Parents/legal guardians of 24-month-old children are included when the child fulfils the inclusion criteria

Exclusion criteria

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

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

•Previous vaccinations with MenACWY vaccine

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

A parent/legal guardian 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 nasopharyngeal carriage rates (certain chromosomal abnormalities or craniofacial abnormalities (like Trisomy 21 or schisis), known or suspected immunodeficiency disease or other medical conditions)

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-08-2018
Enrollment:	760
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	19-09-2018
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 46096
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL7263
NTR-old	NTR7485
CCMO	NL65919.100.18
OMON	NL-OMON46096

Study results