Cross-sectional surveillance study on pneumococcal serotypes and other pathogens in nasopharyngeal samples from infants and parents performed 6.5 years after introduction of pneumococcal vaccination in The Netherlands

Published: 10-07-2012
Last updated: 30-04-2024

Primary: To determine trends in nasopharyngeal colonization with total vaccine- and non-vaccine serotypes of S. pneumoniae in healthy 11-month-old and 24-month-old infants who have been immunized according to the Dutch National Immunization Program...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bacterial infectious disorders
Study type	Observational invasive

Summary

ID

NL-OMON37571

Source
ToetsingOnline

Brief title
Nasopharyngeal colonization in infants and parents/OKIDOKI-3

Condition

- Bacterial infectious disorders

Synonym
asymptomatic pneumococcal nasopharyngeal colonisation, pneumococcal carriage

Research involving

Human

Sponsors and support

Primary sponsor: RIVM
Source(s) of monetary or material Support: Ministerie van VWS

Intervention

Keyword: Infants and parents, Nasopharyngeal colonization, Streptococcus pneumoniae

Outcome measures

Primary outcome

The percentage of total vaccine- and non-vaccine pneumococcal serotypes found in the nasopharyngeal swabs from infants at 11 and 24 months of age by conventional culture. Serotyping is performed at single colony level by Quellung reaction as in previous surveillance studies.

Secondary outcome

The percentage of total vaccine- and non-vaccine pneumococcal serotypes found in the nasopharyngeal swabs from parents of the 24-month-old infants as determined by culture and Quellung.

The percentage of infants and parents with nasopharyngeal swabs positive for S. aureus, H. influenzae and M. catarrhalis as determined by culture.

The percentage of individual pneumococcal serotypes found in the nasopharyngeal swabs from infants at 11 and 24 months of age and parents of the 24-month-old infants as determined by culture and Quellung.

Study description

Background summary

Diseases caused by Streptococcus pneumoniae are always preceded by asymptomatic nasopharyngeal acquisition and colonization. Pneumococcal vaccination reduces acquisition and density of colonization of vaccine-serotype pneumococci in the nasopharynx of vaccinated infants and subsequent transmission to others leading to an indirect protection of the community (herd effects). The vacant niche in the nasopharynx of vaccinated infants is however immediately filled by non-vaccine pneumococci and possibly other potential pathogens that may be involved in respiratory or invasive disease like S. aureus, H. influenzae, M. catarrhalis. Surveillance of nasopharyngeal carriage of pneumococci is important to evaluate shifts in circulation of specific serotypes and to potentially make timely adjustments in the vaccination program. Previous surveillance studies were performed immediately before introduction of pneumococcal vaccination and 3 and 4.5 years after introduction. The nasopharyngeal swabs collected during the current study will be assessed for the concurrent presence of other respiratory pathogens like S. aureus, H. influenzae, M. catarrhalis. As part of one of the exploratory objectives a comparison will be made between the presence of nasopharyngeal pneumococcal serotypes, respiratory non-pneumococcal bacteria (Mycoplasma pneumoniae, Neisseria meningitides, and Bordetella pertussis) and respiratory viruses in infants and parents to those found in elderly subjects, sampled in a parallel study by the same institute. Carriage in the parents is however influenced by the close contacts with their infants who have relatively high carriage rate of S. Pneumoniae. Addition of an extra group of adults with limited contact with children < 6 years will therefore allow a better assessment of a true age-related effect on nasopharyngeal pathogen carriage including a true assessment of the herd effect.

Study objective

Primary:
To determine trends in nasopharyngeal colonization with total vaccine- and non-vaccine serotypes of S. pneumoniae in healthy 11-month-old and 24-month-old infants who have been immunized according to the Dutch National Immunization Program 6.5 years after implementation of PCV-7 and 1.5 years after implementation of PCV-10.

Secondary:
To determine trends in nasopharyngeal pneumococcal colonization with total vaccine- and non-vaccine serotypes in the parents of 24-month-old infants.
To determine trends in colonization of other respiratory pathogens like S. aureus, H. influenzae, M. catarrhalis in infants and parents of 24-month-old infants.
To determine trends in individual serotype colonization in healthy 11-month-old and 24-month-old infants who have been immunized according to the Dutch NIP as well as in parents of 24-month-old infants.

Study design

This is an observational, cross-sectional surveillance study

Study burden and risks

The burden is minimal and the risk associated with participation in this trial is minimal. The study involves only one home visit during which a trained personnel member of the research team will collect a transnasal nasopharyngeal swab and two saliva samples from the infants of 11-and 24-months and participating adults with an additional collection of a transoral nasopharyngeal swab from the adults. Blood samples will be collected on a voluntary basis from the infants and adults. The nose swab may cause a minor self-limiting nose bleeding (less than 1:3000 from own experience). No risk is involved in the saliva sample collection using a sponge in the mouth. The voluntary blood collection is harmless but may be slightly painful and can cause a bruise at the injection site.
The infants participating in this study have already received the vaccinations against pneumococcal disease according to the Dutch National Immunization Program and this is not part of the study. All adults are asked to fill in a small questionnaire together with the visiting researcher. Overall, the home visit will take 45 minutes. The infants and adults themselves have no benefit in participating in this study.

Contacts

Public
RIVM

Antonie van Leeuwenhoeklaan 9
Bilthoven 3721 MA
NL
Scientific
RIVM

Antonie van Leeuwenhoeklaan 9
Bilthoven 3721 MA
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Children (2-11 years)
Elderly (65 years and older)

Inclusion criteria

Infants:
The infants have to be of normal health (same health criteria apply as used in well-baby clinics when an infant receives a vaccination, e.g. also infants with small increases in temperature or cold are seen as infants with normal health)
The parents have to be willing and able to participate in the trial according to procedure
The infant is 11 or 24 months old (± 4 weeks) dependent on the group
The infant has been vaccinated according to the Dutch 3+1 schedule and received 3 pneumococcal vaccinations before the age of 6 months (11-month-old infant) and the 11 month booster (24-month-old infant).
Presence of a signed informed consent signed by both parents/legal representatives.
Parents:
Parents are included when their 24 month-old infant fulfils the inclusion criteria.
Adults with limited contact with children < 6 years:
The adults are aged 20-49 years (both inclusive).
The adults have no contact with children < 6 years for more than 8 hours per week.
The adults have to be willing and able to participate in the trial according to procedure.
Presence of a signed informed consent.

Exclusion criteria

Infants:
Previous vaccinations with pneumococcal vaccine using a schedule that differs from the Dutch 3+1 schedule
Previous vaccinations with other pneumoccocal vaccines than Synflorix (11-month-old infant) or Prevenar-7 (24-month-old infant)
Chromosomal abnormalities or craniofacial abnormalities (like Trisomy 21 or schisis), known or suspected immunodeficiency disease or other medical conditions that will severely affect immunological responses to vaccinations or nasopharyngeal carriage rates.
Coagulation disorder/anticoagulant medication
Parents and adults with limited contact with children < 6 years:

Chromosomal abnormalities or craniofacial abnormalities, known or suspected immunodeficiency disease or other medical conditions that will severely affect immunological responses
Coagulation disorder/anticoagulant medication

Study design

Design

Study phase:	4
Study type:	Observational invasive
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-10-2012
Enrollment:	1320
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	10-valent pneumococcal conjugate vaccine Synflorix

Ethics review

Approved WMO Date:	10-07-2012
Application type:	First submission
Review commission:	METC Noord-Holland (Alkmaar)
Approved WMO Date:	03-09-2012
Application type:	First submission

Review commission:	METC Noord-Holland (Alkmaar)
Approved WMO Date:	28-09-2012
Application type:	Amendment
Review commission:	METC Noord-Holland (Alkmaar)
Approved WMO Date:	02-11-2012
Application type:	Amendment
Review commission:	METC Noord-Holland (Alkmaar)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2012-001458-24-NL
CCMO	NL40288.094.12