Effects of Routine Infant Vaccination With the 7-valent Pneumococcal Conjugate Vaccine on Nasopharyngeal Colonization with Streptococcus pneumoniae in Children and Parents in the Netherlands

Published: 29-07-2008
Last updated: 06-05-2024

Primary:To determine trends in vaccine- and nonvaccine-serotype S. pneumoniae asymptomatic colonisation in healthy 11-month-old and 24-month-old infants who have been immunized according to the Dutch NIP with 7-valent pneumococcal conjugate vaccine...

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

Summary

ID

NL-OMON32500

Source
ToetsingOnline

Brief title
Impact of PCV-7 on pneumococcal carriage in infants and parents

Condition

- Bacterial infectious disorders

Synonym
asymptomatic pneumococcal nasopharyngeal colonisation, pneumococcal carriage

Research involving

Human

Sponsors and support

Primary sponsor: Nederlands Vaccin Instituut
Source(s) of monetary or material Support: Ministerie van VWS,Wyeth

Intervention

Keyword: Infants and parents, Nasopharyngeal colonisation, Pneumococcal conjugate vaccine, Streptococcus pneumoniae

Outcome measures

Primary outcome

The percentage of vaccine and nonvaccine-serotypes found in the nasopharyngeal

swabs at 11 and 24 months of age

Secondary outcome

The percentage of vaccine and nonvaccine-serotypes found in the nasopharyngeal

swabs from the parents of the 24-month-old children

The percentage of children and parents positive for S. aureus, H. influenzae or

M. catarrhalis

Study description

Background summary

All disease caused by Streptococcus pneumoniae is preceded by asymptomatic nasopharyngeal (NP) colonization. The peak age for colonization and person to person transmission is in the first years of life. Apart from protection against invasive pneumococcal disease (IPD), the pneumococcal conjugate vaccine also reduces NP colonisation of vaccine-serotype pneumococci. At the same time, there is an increase of NP colonisation by nonvaccine-serotype pneumococci, filling the ecological niche. Next to IPD monitoring in countries where PCV-7 has been introduced, surveys of NP carriage in vaccine recipients and

non-vaccinated contacts for indirect effects are considered relevant for monitoring of changes in circulating pneumococcal serotypes and predicting herd effects or potential future replacement disease. The aim of the present study is to determine the impact of national PCV-7 implementation on NP pneumococcal carriage in children of 11 and 24 months of age and to evaluate NP colonization of one parent of a 24-month-old child, in the third year after implementation of PCV-7 in the Dutch NIP.

Study objective

Primary:
To determine trends in vaccine- and nonvaccine-serotype S. pneumoniae asymptomatic colonisation in healthy 11-month-old and 24-month-old infants who have been immunized according to the Dutch NIP with 7-valent pneumococcal conjugate vaccine Prevenar®

Secondary objectives
To determine vaccine-and nonvaccine-serotype pneumococcal colonisation in one of the parents of 24-month-old children To determine the influence of altered VT and NVT serotype composition on other colonising bacteria (S. aureus, H.influenzae, M. catarrhalis).

Exploratory:
Exploration of possible trends in serotype-specific colonisation in healthy 11-month-old and 24-month-old infants who have been immunized according to the Dutch NIP with pneumococcal conjugate vaccinations Prevenar®

Study design

Observational study

Study burden and risks

The burden is minimal and the risk associated with participation in this study is minimal since it involves only one home visit during which a transnasal nasopharyngeal swab will be taken by a trained personnel member of the research team. The nose swab may cause a minor, self-limiting nose bleeding (less than 1:1000 from own experience). For the parents, one transnasal and transoral swab will be collected. The nose swab may cause a minor, self-limiting nose bleeding (less than 1:1000 from own experience). Parents and children with coagulation disorders/anticoagulant medication are excluded.
The children participating in the study have been vaccinated acccording to the current Dutch NIP with Prevenar vaccinations.
The parents are ased to fill in a small questionnaire during the home visit together with the member of the research team.

The home visit will take 40 minutes.
The children or parents themselves have no benefit in participating in the study.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

These criteria are derived from the related MINOES study, in order to increase comparability with historical unvaccinated controls
- 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)
-They have to be willing and able to participate in the trial according to procedure

-Presence of a signed informed consent (the parents/legally representatives have given written informed consent after receiving oral and written information)
-The children have received the Prevenar® vaccinations according to the 3+1 schedule of the Dutch NIP
Parents
-Parents are included when the 24-month-old children fulfil inclusion criteria

Exclusion criteria

These criteria are derived from the related MINOES study with PCV-7 unvaccinated children
•Previous vaccinations with Prevenar® using a schedule that differs from the Dutch 3+1 schedule
•Previous vaccinations with other pneumoccocal vaccines
•Previous vaccinations of older brother(s) and/or sister(s) and/or parents with a pneumococcal conjugate vaccine (e.g. brother(s) and/or sister(s) that participated in the MINOES trial)
•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/medication;Parents are excluded
•when they have a bleeding disorder/ anticoagulant medication (because of the transnasal swab)

Study design

Design

Study phase:	4
Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	30-01-2009
Enrollment:	990

Type:	Actual

Ethics review

Approved WMO Date:	29-07-2008
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	23-09-2008
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)

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	EUCTR2008-004972-37-NL
CCMO	NL24116.000.08