Immunogenicity of alternative and reduced immunization schedules using the thirteen-valent polysaccharide conjugate vaccine against infection with Streptococcus pneumoniae.

No registrations found.

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

Summary

ID

NL-OMON26136

Source
Nationaal Trial Register

Brief title
PIM studie

Health condition

Infectious diseases, vaccine preventable diseases, national immunisation programme, immunogenicity, Streptococcus pneumoniae.
Infectieziekten, Rijksvaccinatieprogramma, pneumokokken-vaccinatieschema.

Sponsors and support

Primary sponsor: National Institute for Public Health and the Environment (RIVM), Centre for Infectious Disease Control (CIb).
Source(s) of monetary or material Support: Ministry of Health, Welfare and Sport (VWS).

Intervention

Outcome measures

Primary outcome

The primairy endpoint of this study will be the antibody concentrations against the 13 serotypes of S. pneumoniae included in the vaccine measured at 12 months, 1 month post-booster vaccination. Serum samples will be analysed for specific IgG by a fluorescent-bead-based multiplex immunoassay (MIA).

Secondary outcome

Secondary endpoints are the antibody concentrations at 1 month post-primary, at 8 months and 11 months against the 13 serotypes of S. pneumoniae, and the antibody concentrations against the concomittant vaccines (DTaP-IPV-Hib) to exclude possible interference.

Study description

Background summary

In the Netherlands nationwide pneumococcal vaccination was introduced in June 2006, with a 4-dose schedule in which children receive their vaccinations at 2, 3, 4 and 11 months of age. The reduction of the current 4-dose schedule into a 3-dose pneumococcal vaccination schedule would result in a smaller burden for the children. Furthermore, it would also cause an annual reduction of approximately € 8,000,000 in costs for the National Immunization Program (NIP). However, reduction of the vaccination schedule may also require the use of different vaccination moments e.g. at 3 and 5 months of age. There are 2 reasons for this assumption. First, at a later age the immune system of the infant is more developed and this may result in a better immune response. Second, the primary vaccination series are spread more evenly over the time period where protection of the infant is most needed.

There are 3 objectives within this study:

1. Assessing the optimal PCV vaccination schedule: To assess the effect of the use of pneumococcal vaccination schedules with alternative timing and reduction of the number of vaccination doses on the serological response directed against the different serotypes of pneumococci. This information will be used to investigate whether a different timing or reduction of the vaccination schedule will induce antibody responses that are equal to or better than those obtained by the currently used vaccination schedule. The primairy endpoint for this study will be the antibody titer measured at 12 months, 1 month post-booster.

2. Kinetics of the antibody titer: To assess the kinetics of the pneumococcal antibody titers, in particular in the interval between the last vaccination dose of the primairy series and the booster vaccination at 11 months. This period coincides with the peak incidence of pneumococcal invasive disease and therefore blood samples are taken at 1 month after the

primary series (at 5 or 6 or 7 months of age), at 8 months and 11 months.

3. Interference of vaccination with PCV on other vaccinations: To investigate the possible influence of the pneumococcal vaccination on the serological responses of the other vaccine components of the NIP which are administered simultaneously in the other limb (DTaP-IPVHib).

The study population will consist of 4 groups of each 100 children with the following vaccination schedules:

1. PCV13 at 2-3-4-11 months;

2. PCV13 at 2-4-6-11 months;

3. PCV13 at 2-4-11 months;

4. PCV13 at 3-5-11 months.

All children will receive the DTaP-IPV-Hib vaccination according to the NIP at 2-3-4 and 11 months.

Blood samples will be taken at 1 month after the primary series (at 5 or 6 or 7 months of age), at 8 months of age, at the pre-booster moment (11 months) and one month postbooster (12 months).

The groups of children with the 2 + 1 schedule will be offered an extra vaccination at 24 months to complete their series of pneumococcal vaccinations in accordance with the regular NIP.

The vaccination study described here is in full agreement with the advice of the Health Council and also is proactive as it will be performed using the new 13-valent pneumococcal conjugate vaccine (PCV13, Wyeth) instead of the currently used 7-valent vaccine (PCV7, Wyeth).

Study objective

In the Netherlands nationwide pneumococcal vaccination was introduced in June 2006, with a 4-dose schedule in which children receive their vaccinations at 2, 3, 4 and 11 months of age. The reduction of the current 4-dose schedule into a 3-dose pneumococcal vaccination schedule would result in a smaller burden for the children.
Furthermore, it would also cause an annual reduction of approximately € 8,000,000 in costs for the National Immunization Program (NIP). However, reduction of the vaccination schedule may also require the use of different vaccination moments e.g. at 3 and 5 months of age. There are 2 reasons for this assumption. First, at a later age the immune system of the infant is more developed and this may result in a better immune response. Second, the primary vaccination series are spread more evenly over the time period where protection of the infant is most needed.

The hypothesis is that a different timing and/or reduction of the pneumococcal vaccination schedule will induce antibody responses that are equal to or better than those obtained by the currently used vaccination schedule.

Study design

Blood sample time points are:

1. 1 month after the primary series (5 or 6 or 7 months);

2. 8 months;

3. 11 months (pre-booster);

4. 12 months (post-booster).

Intervention

4 Groups of 100 children:

1. To administer PCV13 at 2-3-4-11 months;

2. To administer PCV13 at 2-4-6-11 months;

3. To administer PCV13 at 2-4-11 months;

4. To administer PCV13 at 3-5-11 months.

All children will receive the DTaP-IPV-Hib vaccination according to the NIP at 2-3-4 and 11 months.

Blood samples will be taken at 1 month after the primary series (at 5 or 6 or 7 months of age), at 8 months of age, at the pre-booster moment (11 months) and one month postbooster (12 months).

The groups of children with the 2 + 1 schedule will be offered an extra vaccination at 24 months to complete their series of pneumococcal vaccinations in accordance with the regular NIP.

Contacts

Public
Postbus 770
Judith Spijkerman

Hoofddorp 2130 AT
The Netherlands
+31 (0)23 8909070
Scientific
Postbus 770
Judith Spijkerman
Hoofddorp 2130 AT
The Netherlands
+31 (0)23 8909070

Eligibility criteria

Inclusion criteria

1. Infants in good general health, eligible to be vaccinated according to the Dutch national vaccination program. The 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;

2. The parents have to be willing and able to allow their child to participate in the trial according to the described procedures;

3. Presence of a signed informed consent in which the parent(s)/legally representative(s) have given written informed consent after receiving oral and written information (signature from one parent in case of alegal representative of an orphan, or single-parent family).

Exclusion criteria

1. Children elegible for the Hepatitis B vaccination;

2. Previous Prevenar and DTaP-IPV-Hib vaccination;

3. Present evidence of serious disease(s) demanding immunosuppressive medical treatment, like cytostatics and prednisolons, that might interfere with the results of the study within 3 months;

4. Any known primary or secondary immunodeficiency;

5. Bleeding disorders;

6. Premature birth (<37 weeks).

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	24-05-2010
Enrollment:	400
Type:	Actual

Ethics review

Positive opinion

Date:	07-05-2010
Application type:	First submission

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
NTR-new	NL2192
NTR-old	NTR2316
Other	Laboratory for Infectious Diseases and Screening : LIS143
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A