Pneumococcal immune response to Synflorix® or Prevenar-13® in infants.

No registrations found.

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

Summary

ID

NL-OMON29635

Source
Nationaal Trial Register

Brief title
PIEN

Health condition

Infectious diseases, Streptococcus pneumonia, pneumococcal vaccination

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 Sports

Intervention

Outcome measures

Primary outcome

1. Cellular immune response (Plasma B cells and memory B cells) immediately before and 7-9 days after the booster at 11-months of age;

2. Humoral immune response (antibody concentrations and geometric mean concentrations

(GMT)) at 12 months of age.

Secondary outcome

1. Opsonophagocytoses immediately before and 7-9 days after the booster at 11-months of age;

2. Avidity at 5, 8, immediately before and 7-9 days after the booster at 11-months and at 12 months of age;

3. Antibody concentrations and geometric mean concentrations (GMT) at 5, 8, immediately before and 7-9 days after the booster at 11-months and at 12 months of age;

4. Kinetics of antibody concentrations and geometric mean concentrations (GMT) over time (at 5, 8, 11 and 12 months of age);

5. DTaP-HIb antibody concentrations and geometric mean concentrations (GMT) at 5, 8, 11 and 12 months of age.

Study description

Background summary

Streptococcus pneumonia (SP) is an important cause of morbidity and mortality worldwide, with the highest incidence of
disease among children < 2 years of age. Streptococcus pneumonia consisting of > 90 known different serotypes, of
which a limited number of about 20 serotypes are known to cause invasive pneumococcal disease (IPD).

Prevenar®, a seven-valent pneumococcal conjugate vaccine (PCV7) was first introduced in the Netherlands immunization
program (NIP) for children born after April 2006. It confers protection against serotypes 4, 6B, 9V, 14, 18C, 19F and 23F. It has been introduced in the NIP for vaccination at 2, 3, 4 and 11 months of age. Recently in 2009, two new
vaccines were registered, which can in due time replace PCV7 in the NIP. All children born after March 2011 will receive
Synflorix®, a ten-valent pneumococcal conjugate vaccine (PCV10) which confers protection against three additional
serotypes. Prevenar-13®, a thirteen-valent pneumococcal conjugate vaccine (PCV13) confers protection against another three extra serotypes, but is not implemented in the NIP.
The current study in combination with our previous KOKKI (cellular immunogenicity after PCV7 vaccination) and PIM
(comparison of 4 different PCV13 vaccination schedules based on humoral immunogenicity)

study can give information on the best vaccination strategy for pneumococcal vaccination. The outcomes of this trial will provide
data on the humoral and cellular immune response of PCV10 and PCV13.

Study objective

Synflorix (PCV10) and Prevenar-13 (PCV13) are comparable in inducing cellular and humoral immune responses in Dutch infants for the 10 overlapping serotypes in the vaccines. Differences are expected for three serotypes that are present in Prevenar-13 but absent in Synflorix.

Study design

1. Humoral response: Month 5, 8, 11 (pre-booster) and 12 (post-booster);

2. Cellular response: Month 11 (pre-booster) and month 11 + 7/9 days (post-booster).

Intervention

1. Pneumococcalpolysaccharide conjugate vaccine (13-valent, adsorbed) (Prevenar-13), 0.5 ml via intramuscular injection at 2, 3, 4 and 11 months;

2. Pneumococcal polysaccharide conjugate vaccine (adsorbed) (Synflorix), 0.5 ml via intramuscular injection at 2, 3, 4 and 11 months.

Contacts

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Eligibility criteria

Inclusion criteria

1. 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 (<38.5C) or cold are seen as children with normal health);

2. The parents/legally representatives 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 (the parents/legally representatives have given written informed consent after receiving oral and written information);

4. PCV13 group: The children are 2 months old (+/-2 weeks), have not received any vaccinations and will receive all vaccinations (DTaP-IPV-Hib-HepB and PCV13) by the study team;

5. PCV10 group: The children are 4-6 months old and have received three DTaP-IPV-Hib-HepB and PCV10 vaccinations according to the 3+1 schedule of the Dutch NIP*.

*The Dutch NIP 3+1 schedule: All children born as of August 1st 2011 will receive Synflorix (PCV10) and DTaP-IPV-Hib-HepB vaccinations, at the age of 2, 3 4 and 11 months of age.

Exclusion criteria

1. PCV13 group: Previous vaccinations with PCV7 or PCV10;

2. PCV10 group: Previous vaccinations with PCV7 or PCV13;

3. PCV10 group: Vaccinations using a schedule that differs from the Dutch 3+1 schedule;

4. Presence of a serious disease that requires medical care that can interfere with the results of the study;

5. Known or expected allergy/hypersensitivity against one of the vaccine ingredients;

6. Known or suspected immunological disorder;

7. Previously administration of plasma products (including immunoglobulin), within three months of study enrolment;

8. Presence of bleeding disorders;

9.Communication problems that interfere with the trial;

10. Prematurity (<37 weeks after gestation).

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	25-10-2011
Enrollment:	160
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	15-09-2011
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	NL2922
NTR-old	NTR3069
Other	Vaccinology : VAC-259
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A