Development of cellular immune response after infant pneumococcal conjugate vaccinations.

No registrations found.

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

Summary

ID

NL-OMON26266

Source
NTR

Brief title
N/A

Health condition

To determine the development of the cellular immune response (plasma B cells and memory B-cells), immediately before and after the booster of the 3+1 Prevenar® vaccination schedule at 11 months of age and before and after the challenge vaccination at 24 months of age.

Sponsors and support

Primary sponsor: Netherlands Vaccine Institute
Source(s) of monetary or material Support: Fund=initiator=sponsor

Intervention

Outcome measures

Primary outcome

- Cellular immunogenicity (plasmacells and memory B-cells frequencies)

Secondary outcome

- Geometric mean titres (GMT)

- Avidity

- Opsonophagocytoses

Study description

Background summary

Prevenar®, a seven-valent pneumococcal conjugate vaccine has been registered for use in a so-called 3+1 vaccination schedule consisting of a three dose primary series followed by a booster vaccination. It has been introduced in the Dutch National Immunization Program in April 2006 for vaccination at 2, 3, 4 and 11 months of age.

Prevenar vaccination provides immediate protection against pneumoccocal related diseases through the induction of functional antibodies, which however only have a short half-life indicating the need for a memory response. Both the induction and maintenance of functional serum antibody titres have a cellular basis which is still poorly understood.

In general, antigens trigger naïve B-cells to expand and differentiate into two types of affinity matured B-cells: antibody secreting plasma B cells and memory B-cells. Since plasma cells are unlikely to persist for more than 6-8 weeks (Gourley TS et al, 2004) maintenance of steady state antibody levels over periods of years requires a continuous low level of differentiation of memory B cells into plasma cells. Factors such as recurrent antigen exposure for example through carriage might be involved in this process.
Prevenar is thought to induce immediate protection through stimulation of antibody production by polysaccharide specific plasma B cells, sustained protection is conferred by a memory B cell pool which induces an accelerated increase in antibody titres during secondary immune responses seen after re-infection or boosting.
An improved understanding of the immunobiology of the B-cell response to conjugate vaccines, such as Prevenar, is essential to develop immunization strategies that provide sustained protection.

Study objective

Prevenar® is thought to induce immediate protection through stimulation of antibody production by polysaccharide specific plasma B cells, sustained protection is conferred by a memory B cell pool which induces an accelerated increase in antibody titres during secondary immune responses seen after re-infection or boosting.

Study design

- inclusion: 6 months

- evaluation: 3 months

Intervention

4 groups of children, in all groups the children will have 1 blood collection. The children in group 4 (n=25) receive a challenge vaccination of Prevenar® at 24 months of age.

Contacts

Public
Laboratorium voor Vaccin Onderzoek, PB 117
Nederlands Vaccin Instituut (NVI)
Antwoordnummer 3205

D.E. Kleijne
Bilthoven 3720 BA
The Netherlands
+31 (0)30 2742305
Scientific
Laboratorium voor Vaccin Onderzoek, PB 117
Nederlands Vaccin Instituut (NVI)
Antwoordnummer 3205

D.E. Kleijne
Bilthoven 3720 BA
The Netherlands
+31 (0)30 2742305

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 or cold are seen as children with normal health)

2. They 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. The children have received or will receive the Prevenar® vaccinations according to the 3+1 schedule of the Dutch NIP

Exclusion criteria

1. Previous vaccinations with Prevenar® using a schedule that differs from the Dutch 3+1 schedule

2. Previous vaccinations with other pneumoccocal vaccines

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

4. Known or expected allergy/hypersensitivity against one of the vaccine ingredients (anamnestic, be alert if the child has had medical complaints after previous Prevenar® vaccinations)

5. Known or suspected immunological disorder

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

7. Bleeding disorders

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-12-2008
Enrollment:	100
Type:	Actual

Ethics review

Positive opinion

Date:	17-11-2008
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	NL1469
NTR-old	NTR1538
Other	: NVI-248
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results

N/A