Study of the long-term immune response after pertussis vaccination

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON29115

Source
NTR

Brief title
KIM-studie (in Dutch: Kinkhoest IMmunisatie)

Health condition

Pertussis
Vaccination
cellular immunity
humoral immunity

In dutch:
Kinkhoest
Vaccinatie
cellulaire immuniteit
humorale immuniteit

Sponsors and support

Primary sponsor: National Institute for Public Health and the Environment (RIVM)
Source(s) of monetary or material Support: National Institute for Public Health and the Environment (RIVM)

Intervention

Outcome measures

Primary outcome

• To assess pertussis specific IgG antibody levels in serum to determine the effects of a preadolescent aP booster vaccination and determine whether there is a difference in IgG levels between wP and aP primed children at 8-9 years of age;

• To assess memory B- and T-cell responses against the various B. pertussis proteins to determine the effects of a preadolescent aP booster vaccination and determine whether there is a difference between wP and aP primed children at 8-9 years of age.

Secondary outcome

• To assess pertussis specific IgG-subclasses and -avidity;

• To measure serum specific IgG-antibodies, -subclasses and -avidity and memory B- and T-cell responses against the other vaccine components (Diphtheria, Tetanus, Polio, Mumps, Measles and Rubella);

• To measure serum specific IgG-antibodies, -subclasses and -avidity against other vaccine components from the NIP;

• To measure IgA- and IgE- antibodies in serum against the proteins of B. pertussis and other vaccine components from the NIP.

Study description

Background summary

Pertussis, or whooping cough, is caused by the bacterium Bordetella pertussis and is an acute and serious respiratory infection. Since the introduction of whole-cell pertussis (wP) vaccines in 1953 in the Netherlands, the incidence of pertussis reduced rapidly. However, despite high vaccination coverage (95%) pertussis is re-emerging in the Netherlands since 1996. This phenomenon is also observed in other western countries with high vaccination coverage like Finland, Germany, the USA, Canada, Australia and Japan. The introduction of an acellular pertussis (aP) vaccine for children 4 years of age in 2001 in the Netherlands resulted in a shift of peak prevalence from 4-6 year old children in 2001 to 8-15 years of age in 2012. Since January 1st 2005, all children are vaccinated with aP vaccines in the combination vaccine DTaP-IPV-Hib in the first year of life. Studies in the US showed a difference in the chance of acquiring pertussis between children vaccinated with aP or wP. Children vaccinated

with aP had significant more reported pertussis than children who received at least one wP vaccination. However, in our previous study (ISRCTN65428640) we showed that one month after an aP booster vaccination at 4 years of age, children being primed with wP had significant lower numbers of PT- and Prn-specific memory B-cells compared with children who have been primed with aP.
The main purpose of this study is to assess the long-term antibody responses and cellular memory immunity against B. pertussis in a cohort of 80 Dutch children, 8-9 years of age, who have been vaccinated with aP in the first year of life. Furthermore, the effects of a second aP booster on humoral- and cellular memory- immunity one month and one year after booster vaccination will be investigated in this cohort, since peak-incidence of pertussis is now highest in 80 children 8-15 years of age. These insights are necessary to evaluate the current protection against pertussis in this age group and to understand the possible effects of a second aP booster vaccination on long-term immunity against pertussis.

Study objective

Since 1996, a rise in notifications of pertussis (whooping cough) is observed in the Netherlands. In 2012, the largest epidemic peak occurred since pertussis became a notifiable disease in 1976 in the Netherlands. During this epidemic, more than 13.000 cases were reported and 3 unvaccinated neonates between 0-2 months died. In numerous other countries in and outside of Europe, epidemics of pertussis are reported. Due to the increased pertussis incidence, a preschooler booster vaccination was introduced in the Netherlands in 2001 for 4 year old children. This booster vaccination consists of acellular pertussis (aP) components. After the introduction of this booster vaccine, peak prevalence shifted from 4-6 year old children in 2001 to 8-15 year olds in 2012. More reported pertussis cases are also found in adults. Several other countries have similar peak prevalence in (pre-) adolescents. Some countries, like Germany, introduced an (pre-) adolescent booster vaccination to protect this age group of pertussis. Whether this (pre-) adolescent booster vaccination mounts in long-term protection against pertussis is still unclear.

This study aims to get insights in the long-term humoral and cellular memory immunity against Bordetella pertussis, and the possible relationship between cellular and humoral immune responses, in children 8-9 years of age, who have been primed and boostered with aP vaccines. Furthermore, since peak-incidence of pertussis is now highest in children 8-15 years of age, we will investigate the longitudinal effects of a pre-adolescent aP booster vaccination in aP-primed children 8-9 years of age, on the humoral and cellular memory immunity, before and one month and one year after the pre-adolescent aP booster vaccination.

Study design

T0 = vaccination (start of study)
T1 = one month after vaccination
T2 = one year after vaccination

Intervention

Single vaccination with Tdap at first study visit.
3 blood sample collections. before vaccination, one month and one year after vaccination.

Contacts

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Eligibility criteria

Inclusion criteria

• Good general health;

• 8-9 years of age;

• Vaccinated with Infanrix-IPV + Hib (GSK) at 2, 3, 4, and 11 months of age and with Infanrix-IPV (GSK) at 4 years
of age;

• Received all other regular vaccines according to the Dutch National Immunization Program (NIP);

• Provision of written informed consent by both parents or legal representatives;

• Adherent to protocol and available during the study period.

Exclusion criteria

• Present evidence of serious disease(s) demanding immunosuppressive medical treatment, like corticosteroids,
that might interfere with the results of the study. Treatment within the 3 months before the study (chronic infection,
clotting disorder, genetic disorder);

• Serious infection disease or fever (>38.5°C) within 14 days before the vaccination;

• Antibiotic use within 14 days before vaccination;

• Any known primary or secondary immunodeficiency;

• Previous administration of plasma products (including immunoglobulins) within the last 6 months;

• Vaccination with any other pertussis vaccine than those described in the inclusion criteria (i.e. vaccinated with
Pediacel or Triaxis (both from Sanofi Pasteur MSD));

• Vaccination other than those used in the NIP within a month before vaccination/ blood sampling;

• (suspected) Presence of allergy against (one of the) components of het vaccine;

• In the past an allergic reactions after vaccination;

• Neurologic condition (like epilepsy).

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)

Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	30-09-2013
Enrollment:	80
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

ID: 50356
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL3918
NTR-old	NTR4089
CCMO	NL44640.100.13
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON50356

Study results

Summary results
N/A