Study of the long-term immune response after pertussis vaccination

Gepubliceerd: 25-07-2013 Laatst bijgewerkt: 15-05-2024

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....

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON29115

Bron
NTR

Verkorte titel
KIM-studie (in Dutch: Kinkhoest IMmunisatie)

Aandoening

Pertussis
Vaccination
cellular immunity
humoral immunity

In dutch:
Kinkhoest
Vaccinatie
cellulaire immuniteit
humorale immuniteit

Ondersteuning

Primaire sponsor: National Institute for Public Health and the Environment (RIVM)
Overige ondersteuning: National Institute for Public Health and the Environment (RIVM)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

• 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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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

Contactpersonen

Publiek

Postbus 1

Saskia Lee, van der

Bilthoven 3720 BA
The Netherlands
033-2743407

Wetenschappelijk

Postbus 1

Saskia Lee, van der
Bilthoven 3720 BA
The Netherlands
033-2743407

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

• 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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

• 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).

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	30-09-2013
Aantal proefpersonen:	80
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing
Soort: Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 50356
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten
N/A