Long-term memory immunity against Bordetella pertussis in children 9 years of age who have been vaccinated with acellular pertussis vaccines: effect of an extra preadolescent acellular booster vaccination

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bacterial infectious disorders
Study type	Interventional

Summary

ID

NL-OMON50356

Source
ToetsingOnline

Brief title
Pertussis Immunization study

Condition

- Bacterial infectious disorders

Synonym
Vaccination against Pertussis

Research involving

Human

Sponsors and support

Primary sponsor: RIVM
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Cellular, Humoral, Immunity, Pertussis

Outcome measures

Primary outcome

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

• To measure serum specific IgG-antibodies and cellulair immune responses

against other infectious diseases occurring in Dutch children.

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, our previous *Memory-study* (ISRCTN65428640) 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.

Study objective

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 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, one year and six years after booster vaccination will be investigated in this cohort, since peak-incidence of pertussis is now highest in 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 design

Longitudinal intervention study

Intervention

Participants will receive one injection of DTaP-IPV (Boostrix Polio® (GSK)) combination vaccine intramuscularly in the upper arm as a replacement of the normal DT-IPV vaccine. Venapunctures will be performed prior to and one month and one year after vaccination. Six years after vaccination the participant/parent will perform a fingerprick at home.

Study burden and risks

Participants will benefit from participating in this study by receiving an additional pertussis vaccination. From the public health perspective, participation in this study will contribute to the improvement of the NIP. Vaccination, venapunctures and vingerprick might be painful and unpleasant, however, they are relative low risk invasive procedures. On request of the participant, Xylocaine® spray can be used to reduce possible local pain during the venapunction. Boostrix Polio® is a registered vaccine in the Netherlands. Mild adverse reactions to the vaccine may occur but they are expected to be mainly local and transient. Severe allergic reactions to one of the vaccine components are unlikely to occur. As a compensation for the vaccination, venapunctures and the fingerprick, all participants will receive a total of ¤32,50 in vouchers.

Contacts

Public
RIVM

Antonie van Leeuwenhoeklaan 9
Bilthoven 3721 MA
NL
Scientific
RIVM

Antonie van Leeuwenhoeklaan 9
Bilthoven 3721 MA
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

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 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/ venapuncture;
• (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 phase:	4
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	30-09-2013
Enrollment:	80
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Boostrix IPV

Ethics review

Approved WMO Date:	31-05-2013
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	22-07-2013
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	05-12-2019

Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	11-12-2019
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	13-05-2020
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	19-05-2020
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 29115
Source: NTR
Title:

In other registers

Register	ID
EudraCT	EUCTR2013-001864-50-NL
ISRCTN	ISRCTN65428640
CCMO	NL44640.100.13
OMON	NL-OMON29115

Study results

Results posted: 17-10-2023

First publication
01-01-1900

URL result
Type
ext
Naam
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URL