Memory response against Bordetella pertussis in adults: immunological effects of an acellular pertussis 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-OMON50704

Source
ToetsingOnline

Brief title
VIKING-study

Condition

- Bacterial infectious disorders

Synonym
Adult vaccination against Bordetella pertussis

Research involving
Human

Sponsors and support

Primary sponsor: RIVM

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

Intervention

Keyword: Adults, Humoral, Immunity, Pertussis

Outcome measures

Primary outcome

• To assess pertussis specific IgG antibody levels in serum prior to vaccination (T0) and 14 days (T1), 28 days (T2), 1 year (T3), 2 years (T4) and 6 years (T5) after vaccination to determine the kinetics of pertussis specific antibody levels after an aP booster vaccination in adults 25-29 years of age;

• To assess memory B- and T-cell responses against the various B. pertussis proteins at all time points to determine the effects of an aP booster vaccination in adults 25-29 years of age (prior to vaccination, 14 days, 28 days, 1 year and, 2 years after vaccination.

Secondary outcome

• To determine pertussis specific IgG-subclasses and -avidity in serum (T0-T4);

• To determine pertussis specific IgG-antibodies in saliva (T0-T4);

• To measure serum specific IgG-antibodies (T0-T5), and memory B- and T-cell responses (T0-T4) against the other components (Diphtheria and Tetanus) of the booster vaccine;

• To measure pertussis specific IgA antibodies in serum and saliva (T0-T4).

Study description

Background summary

Pertussis, or whooping cough, is caused by the bacterium Bordetella pertussis and is an acute and serious respiratory infection, in particular for young and unvaccinated children. Since the introduction of whole-cell pertussis (wP) vaccines in 1953 in the Netherlands, the incidence of pertussis in childhood reduced rapidly. However, despite high vaccination coverage (95%), pertussis is re-emerging in the Netherlands since 1996. This phenomenon is also observed in most other western countries with high vaccination coverage. The most recent epidemic in 2012 in the Netherlands highlighted the vulnerability of infants for a pertussis infection since three infants died. Vaccine derived protection against pertussis is not yet established in the first months of life. The pertussis incidence in adults increases as well. Prolonged cough episodes is one of the symptoms adults suffer from.
The main purpose of this study is to investigate the longitudinal effects of an aP booster vaccination in adults, on long-term humoral and cellular memory immunity against B. pertussis. By measuring antibody levels against the various pertussis proteins, antibody kinetics in serum and saliva can be determined. These insights are necessary to understand the possible effects of an adult aP booster vaccination on long-term immunity against pertussis. If the decay of vaccine induced antibody levels is limited for a long period, these antibodies could help protect an infant when antibodies cross the placenta during pregnancy.

Study objective

The main purpose of this study is to investigate the longitudinal effects of an aP booster vaccination in adults, on long-term humoral and cellular memory immunity against B. pertussis. By measuring antibody levels against the various pertussis proteins, antibody kinetics in serum and saliva can be determined.

Study design

Longitudinal intervention study

Intervention

Participants will receive one injection of Tdap (tetanus, reduced diphtheria and reduced acellular pertussis) (Boostrix® (GSK)) combination vaccine intramuscular in the upper arm. Blood and saliva samples will be drawn before, at two and four weeks and one and two years after vaccination.

Study burden and risks

Participants will benefit from participating in this study by receiving an additional Tdap vaccination. From the public health perspective, participation in this study will contribute to insight in pertussis immunity. Vaccination, venapunctures and fingerpricks are unpleasant at the moment of injection,

however, they are low risk invasive procedures. Boostrix® is a registered vaccine in the Netherlands. 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. Tdap booster vaccination in adults is a common procedure in several countries already. As a compensation for the vaccination, venapunctures, the fingerprick, and the saliva drawings, all participants will receive a total of ¤37,50 in vouchers.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

In order to be eligible to participate in this study, participants must meet all of the following criteria:
• Good general health;

• 25-29 years of age;
• Vaccinated with DTwP-IPV (RIVM) at 3, 4, 5, and 11 months of age;
• Received all other regular vaccines according to the Dutch NIP;
• Provision of written informed consent;
• Adherent to protocol and available during the study period.

Exclusion criteria

Any of the following criteria will exclude a participant from this study:
• Antibiotic use within 14 days of enrollment;
• Present evidence of serious disease(s) demanding immunosuppressive medical treatment, like corticosteroids, that might interfere with the results of the study within the last 3 months;
• Known or suspected allergy to any of the vaccine components (by medical history);
• Occurrence of serious adverse event after primary DTwP-IPV vaccination or other vaccination (by medical history);
• Known or suspected immune deficiency;
• History of any neurologic disorder, including epilepsy;
• Previous administration of serum products (including immunoglobulins) within 6 months before vaccination and blood/ saliva sampling;
• Vaccination with any other pertussis vaccine than those described in the inclusion criteria;
• No DT or DT-IPV vaccination at least 5 years before enrollment;
• Vaccination within a month before enrollment;
• Pregnant at start of study (when vaccination is administered);

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):	22-04-2014
Enrollment:	100
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Boostrix

Ethics review

Approved WMO Date:	24-02-2014
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	06-03-2014
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	24-04-2020
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	04-05-2020
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: 28859
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
EudraCT	EUCTR2013-005355-32-NL
CCMO	NL47382.094.13
OMON	NL-OMON28859

Study results

Date completed:	01-01-1900
Results posted:	17-10-2023
Actual enrolment:	106

First publication
01-01-1900

URL result
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