Study the immune responses after pertussis vaccination in adults

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28859

Source
NTR

Brief title
VIKING-studie

Health condition

Whooping cough, pertussis, vaccination, cellular immunity, humoral immunity

Sponsors and support

Primary sponsor: Rijksinstituut voor Volksgezondheid en Milieu (RIVM)
Source(s) of monetary or material Support: Rijksinstituut voor Volksgezondheid en Milieu (RIVM)

Intervention

Outcome measures

Primary outcome

• To assess pertussis specific IgG antibody levels in serum at T0 (prior to vaccination), 14 days (T1), 28 days (T2), 1 year (T3) and 2 (T4) years 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 vaccine proteins at all time points to determine the effects of an aP booster vaccination in adults 25-29 years of age.

Secondary outcome

• To determine pertussis specific IgG-subclasses and –avidity in serum;

• To determine pertussis specific IgG-antibodies in saliva;

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

• To measure pertussis specific IgA antibodies in serum and saliva.

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 longterm
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. In addition, if the decay of vaccine induced antibody levels is limited for a long period in women, these antibodies could help protect an infant when specific pertussis antibodies are transported across the placenta during pregnancy.

Study design

T0 (prior to vaccination), 14 days (T1), 28 days (T2), 1 year (T3) and 2 (T4) years after vaccination

Intervention

Single vaccination with Tdap at first study visit. 5 blood- and saliva-sample collections. before vaccination, two weeks, four weeks, one year and two years after vaccination.

Contacts

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Eligibility criteria

Inclusion 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

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	21-04-2014
Enrollment:	100
Type:	Anticipated

Ethics review

Positive opinion

Date:	07-04-2014
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 50704
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL4256
NTR-old	NTR4494
CCMO	NL47382.094.13
OMON	NL-OMON50704

Study results

Summary results
N/A