# The longitudinal kinetics of long term cellular memory immunity against Bordetella pertussis in Dutch 8-9 years old children after ACV booster vaccination.

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The assessment of the duration of the cellular immunity to Bordetella pertussis after an extra ACV booster and the relationship between the memory B- cells and antibody responses. The methods used in the study are:B- and T- cell memory responses and...

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| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Other condition |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON39529

**Source**
ToetsingOnline

**Brief title**
Booster study

### Condition

- Other condition
- Bacterial infectious disorders

**Synonym**
pertussis, whooping cough

**Health condition**

immunologie na vaccinatie

**Research involving**
Human

## Sponsors and support

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

## Intervention

**Keyword:** bordetella pertussis, immunity, vaccination

## Outcome measures

### Primary outcome

The main study parameters will be pertussis specific memory B- and T- cell

responses as well as antibody levels and affinity against the various proteins

of pertussis and the other components of the DTPacv-IPV-Hib vaccin.

### Secondary outcome

If there are enough lymphocytes, the immune response (memory B- and T-cells and

antibody responses) to other vaccine preventable diseases, like measles, mumps,

diphtheria, tetanus and polio will also be measured.

# Study description

### Background summary

Since the incidence of whooping cough (pertussis) is increasing in the Netherlands, the effect of vaccination against Bordetella pertussis needs to be addressed.
Because of the increasing incidence of whooping cough at the age of 4, an acellular booster vaccination (ACV) at 4 years of age is introduced in the Netherlands in 2001. However, nowadays the peak incidence of whooping cough in children has shifted to 8-9 years old children. In addition, we also see a rise in notifications in adolescents and adults. Therefore, in some countries, e.g. Germany and France, an extra acellular booster vaccination has been given to the 9-14 years old children. Also in Belgium they will introduce an extra

booster vaccination in 14-16 years old children. Because of the shift in the prevalence peak, the effect of the booster vaccination on the long term immunity against Bordetella pertussis needs to be addressed in this specific age group.
This study aims to investigate the longitudinal kinetics of the effect of the ACV booster vaccination on the memory B- and T- cell immunity in children who are primary vaccinated with whole cell vaccine (WCV) and boostered with ACV. Furthermore, the relationship between the cellular immunity and the antibody responses after ACV booster will be addressed in order to gain insight if further booster vaccinations are required.

### Study objective

The assessment of the duration of the cellular immunity to Bordetella pertussis after an extra ACV booster and the relationship between the memory B- cells and antibody responses.
The methods used in the study are:
B- and T- cell memory responses and antibody levels against the various components present in the acellular pertussis vaccine.

### Study design

Intervention study: An extra ACV booster vaccination will be given to children of 8-9 years old. One pre-vaccination blood sample will be taken and three post-vaccination blood samples will be taken at 28 days, 1 year and 5.5-6 years in which the frequency of memory B- cells will be assessed. In a control group children who have received the regular DTP vaccination without the extra pertussis vaccination will be recruited and one blood sample will be taken 1 year after the regular DTP vaccination.
A control group for the fourth bloodsamples (5.5-6 years post vaccination) comprises participants of an other RIVM study. This study investigates the appropriate age for a second Meningococcal serogroup C vaccination (TIM-studie; NL 35207.100.11). Blood samples will be collected for the TIM-study in children 15 years of age. No extra blood sample is required for the control group 5.5-6 years post ACV vaccination.

Questionnaires including questions concerning clinical manifestations of whooping cough will also be completed.

### Intervention

The combination vaccine DTPacv-IPV (Boostrix polioTM) produced by GSK containing a 3 component ACV (Pertussis toxin (Ptx), filamentous hemagglutinin (FHA) and pertactin (Prn), tetanustoxoid, difterietoxoid and inactivated polio virus, will be given 8-9 years old children who received the DTPwcv-IPV-(Hib) at 2,3,4 and 11 months old and DTP + a three component ACV (Monovalent ACV by

GlaxoSmithKline (GSK)) as a booster vaccination at 4 years old. The extra pertussis vaccination is combined with the DT-IPV and MMR vaccination which they receive in the regular immunization program. One pre- and three post-vaccination (28 days, 1 year and 5.5-6 year) blood samples will be taken. In the control group one blood sample will be taken 1 year after the regular DTP vaccination.
A control group for the fourth bloodsamples (5.5-6 years post vaccination) comprises participants of an other RIVM study. This study investigates the appropriate age for a second Meningococcal serogroup C vaccination (TIM-studie; NL 35207.100.11). Blood samples will be collected for the TIM-study in children 15 years of age. No extra blood sample is required for the control group 5.5-6 years post ACV vaccination.

### Study burden and risks

Memory B- and T- cell immunity and the relationship between memory B- cells and antibody responses after a booster with an acellular pertussis vaccine will be addressed. This requires a blood sample of 15 ml per child pre- and post-vaccination (total of three blood samples). A volume of 15 ml is needed to be able to do all the memory B- cell tests against the five most important proteins of Bordetella pertussis. With less material, B- cell responses against just one or two proteins of pertussis will be measured. A questionnaire will be used to relate immune functions to clinical manifestations of whooping cough. We expect 5% of all parents to consent in participation based on our experiences with a previous study. The total number needed will be 70 children. There will be no risk for the participants. In the controlgroup 20 children will participate.

## Contacts

**Public**
RIVM

Antonie van Leeuwenhoeklaan 9
Bilthoven 3720 BA
NL
**Scientific**
RIVM

Antonie van Leeuwenhoeklaan 9
Bilthoven 3720 BA
NL

# Trial sites

## Listed location countries

Netherlands

# Eligibility criteria

**Age**
Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)

## Inclusion criteria

A population of healthy, Dutch 8-9 years old children who received four vaccinations at 2,3,4 and 11 months with DTPwcv-IPV-(Hib) and a booster vaccination at 4 years old with a three component ACV will be recruited.

## Exclusion criteria

Any of the following criteria will exclude a volunteer from participation, at start of the study:
• Present evidence of serious disease(s) demanding immunosuppressive medical treatment, like corticosteroids that might interfere with the results of the study within 3 months.
• Any known primary or secondary immunodeficiency.

# Study design

## Design

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| Study phase: | 4 |
| Study type: | Interventional |
| Intervention model: | Other |
| Allocation: | Non-randomized controlled trial |
| Masking: | Open (masking not used) |

**Primary purpose:** Other

## Recruitment

NL

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|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 18-03-2009 |
| Enrollment: | 90 |
| Type: | Actual |

## Medical products/devices used

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| Product type: | Medicine |
| Brand name: | Boostrix polio |

# Ethics review

Approved WMO

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| Date: | 23-09-2008 |
| Application type: | First submission |
| Review commission: | CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag) |

Approved WMO

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|---|---|
| Date: | 23-12-2008 |
| Application type: | First submission |
| Review commission: | CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag) |

Approved WMO

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|---|---|
| Date: | 09-02-2010 |
| Application type: | Amendment |
| Review commission: | CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag) |

Approved WMO

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|---|---|
| Date: | 09-09-2014 |
| Application type: | Amendment |
| Review commission: | CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag) |

# Study registrations

## Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

## In other registers

| Register | ID |
|---|---|
| EudraCT | EUCTR2008-002378-37-NL |
| CCMO | NL23149.000.08 |