

Booster study: long term cellular memory immunity against Bordetella pertussis

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| Submission date 23/04/2008 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered |
| | | <input type="checkbox"/> Protocol |
| Registration date 05/03/2009 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan |
| | | <input checked="" type="checkbox"/> Results |
| Last Edited 13/05/2015 | Condition category Infections and Infestations | <input type="checkbox"/> Individual participant data |

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
LIS-142

Study information

Scientific Title

The longitudinal kinetics of long term cellular memory immunity against Bordetella pertussis in Dutch 8 to 9 year old children after acellular pertussis vaccine (ACV) booster vaccination

Study objectives

Whooping cough is a respiratory disease, caused by Bordetella pertussis. Whooping cough is a serious disease in the young, vulnerable infant. Older children and adults are the main source of infection.

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 pertussis vaccine (ACV) booster vaccination at 4 years of age was introduced in the Netherlands in 2001. However, nowadays the peak incidence of whooping cough in children has shifted to 8 to 9 year 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 to 14 year old children. Also in Belgium they will introduce an extra booster vaccination in 14 to 16 year 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 of B- and T-cell immunity in children who are primary vaccinated with whole cell vaccine (WCV) and boosted 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.

On 13/05/2015 the following changes were made to the trial record:

1. The overall trial end date was changed from 01/06/2010 to 11/11/2014.
2. The target number of participants was changed from 70 to 86.

Ethics approval required

Old ethics approval format

Ethics approval(s)

The Dutch Central Committee on Research involving Human Subjects (CCMO), 23/12/2008, ref: NL 23149.000.08

Study design

Single-centre interventional single-arm non-randomised study

Primary study design

Interventional

Secondary study design

Non randomised study

Study setting(s)

Hospital

Study type(s)

Prevention

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Whooping cough

Interventions

The combination vaccine diphtheria, tetanus, pertussis acellular vaccination, poliomyelitis (DTPacv-IPV) (Boostrix polio™, 0.5 ml) produced by GlaxoSmithKline (GSK) containing a three-component ACV (pertussis toxin [Ptx], filamentous haemagglutinin [FHA] and pertactin [Prn]), tetanustoxoid, diphtherietoxoid and inactivated polio virus, will be given intramuscularly to 8 to 9 year old children who received the DTPwcv-IPV-(Hib) at 2, 3, 4 and 11 months old and DTP and a three component ACV (monovalent ACV by GSK) as a booster vaccination at 4 years old. The extra pertussis vaccination is combined with the DT-IPV and measles, mumps and rubella (MMR) vaccination which they receive in the regular immunisation program. One pre- and two post-vaccination (28 days and 1 year) blood samples will be taken.

Added 13/05/2015:

In addition, from a subset of children, a blood sample will be collected 5.5 years after vaccination.

Intervention Type

Biological/Vaccine

Primary outcome measure

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 vaccine.

Secondary outcome measures

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.

Overall study start date

01/02/2009

Completion date

11/11/2014

Eligibility

Key inclusion criteria

1. Healthy 8 to 9 year old children, either sex
2. Received four vaccinations at 2, 3, 4 and 11 months with diphtheria, tetanus, pertussis whole

cell vaccine, poliomyelitis - haemophilus influenzae type b (DTPwcv IPV-Hib)
3. Received a booster vaccination at 4 years old with a three component ACV

Participant type(s)

Patient

Age group

Child

Lower age limit

8 Years

Upper age limit

9 Years

Sex

Both

Target number of participants

86

Key exclusion criteria

Any of the following criteria will exclude a volunteer from participation, at start of the study:

1. Present evidence of serious disease(s) demanding immunosuppressive medical treatment, like corticosteroids that might interfere with the results of the study within three months
2. Any known primary or secondary immunodeficiency

Date of first enrolment

01/02/2009

Date of final enrolment

09/04/2009

Locations**Countries of recruitment**

Netherlands

Study participating centre

National Institute of Public Health and Environmental Protection (RIVM)

Bilthoven

Netherlands

3720 BA

Sponsor information

Organisation

National Institute of Public Health and Environmental Protection (RIVM) (Netherlands)

Sponsor details

Antoni van Leeuwenhoeklaan 9
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Sponsor type

Research organisation

Website

<http://www.rivm.nl>

ROR

<https://ror.org/01cesdt21>

Funder(s)

Funder type

Research organisation

Funder Name

National Institute of Public Health and Environmental Protection (RIVM) (Netherlands)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---------------------------------|---------|--------------|------------|----------------|-----------------|
| Results article | results | 09/12/2011 | | Yes | No |
| Results article | results | 01/12/2012 | | Yes | No |