ISRCTN64117538 https://doi.org/10.1186/ISRCTN64117538

Booster study: long term cellular memory immunity against Bordetella pertussis

Submission date	Recruitment status	[_] Prospectively registered
23/04/2008	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
05/03/2009	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
13/05/2015	Infections and Infestations	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Ms Saskia van der Lee

Contact details
National Institute of Public Health and Environmental Protection (RIVM)
Antoni van Leeuwenhoeklaan 9
Bilthoven
Netherlands
3720 BA
+31 (0)30 274 3407
Saskia.van.der.lee@rivm.nl

Additional identifiers

Protocol serial number
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 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.

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

Primary study design
Interventional

Study design
Single-centre interventional single-arm non-randomised study

Study type(s)
Prevention

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, difterietoxoid 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(s)
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.

Key secondary outcome(s)
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.

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

Healthy volunteers allowed
No

Age group
Child

Lower age limit
8 Years

Upper age limit
9 Years

Sex
All

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)

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

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