Immunogenicity and adjuvant effect of the whole cell Pertussis component of the Dutch combined Diphtheria, Tetanus, Pertussis, Poliomyelitis - Haemophilus influenzae type b vaccine in infants compared to the old whole cell P vaccine and a new acellular P vaccine component

Submission date	Recruitment status	Prospectively registered
02/05/2007	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
02/05/2007	Completed	Results
Last Edited	Condition category	Individual participant data
23/09/2021	Infections and Infestations	Record updated in last year

# Plain English summary of protocol

Not provided at time of registration

# **Contact information**

# Type(s)

Scientific

#### Contact name

Dr G. Berbers

#### Contact details

National Institute for Public Health and the Environment (RIVM) P.O. Box 1 Bilthoven Netherlands 3720 BA +31 (0)30 274 2496 guy.berbers@rivm.nl

# Additional identifiers

### Protocol serial number

LTR134

# Study information

### Scientific Title

Immunogenicity and adjuvant effect of the whole cell Pertussis component of the Dutch combined Diphtheria, Tetanus, Pertussis, Poliomyelitis - Haemophilus influenzae type b vaccine in infants compared to the old whole cell P vaccine and a new acellular P vaccine component

### Acronym

aKwK trial

### Study objectives

To compare the immunogenicity of the whole cell (DTwP) versus the acellular (DTaP) pertussis component of the Diphtheria, Tetanus, Pertussis, Poliomyelitis - Haemophilus influenzae type b (DTP IPV-Hib) vaccine as measured by the antibody titres at 11 months before the fourth vaccination and at 12 months.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Approval received from the CCMO (Central Committee on Research inv. Human Subjects) on the 18th October 2004 (ref: P04.1099C)

### Study design

Interventional, non-randomised, non-controlled, parallel group trial

### Primary study design

Interventional

# Study type(s)

Prevention

# Health condition(s) or problem(s) studied

Pertussis, whooping cough

### **Interventions**

Four groups of 75 children aged 11 months:

- 1. DTwP IPV-Hib primary series and booster (11 months) (n = 32)
- 2. DTwP IPV-Hib primary series and DTaP IPV-Hib booster (Infanrix) (n = 79)
- 3. DTaP IPV-Hib (Infanrix) primary series and booster (n = 95)
- 4. DTaP IPV-Hib (Pediacel) primary series and booster with (n = 75) and without (n = 75) pneumococcal vaccination (Prevenar)

### Intervention Type

Drug

#### Phase

### Drug/device/biological/vaccine name(s)

Diphtheria, Tetanus, Pertussis, Poliomyelitis - Haemophilus influenzae type b (DTP IPV-Hib) vaccine

### Primary outcome(s)

To compare the immunogenicity of the whole cell versus the acellular pertussis component of the DTP IPV-Hib vaccine as measured by the antibody titres at 11 months before the fourth vaccination and at 12 months. The antibody titres are determined by a twofold serial dilution Enzyme Linked Immunosorbent Assay (ELISA).

### Key secondary outcome(s))

Antibody titres for all vaccine components are measured at 11 months before vaccination and at four to eight weeks after the fourth DTP IPV-Hib vaccination. This will also allow to investigate:

- 1. The effect of the changes in the production process of the Pertussis whole cell component compared to the old whole cell component (data on file)
- 2. The adjuvant effect of the whole cell versus two different acellular Pertussis components in the DTP IPV-Hib vaccine as used in The Netherlands
- 3. The immunogenicity and the adjuvant effect of the two different acellular Pertussis components in the DTP IPV-Hib vaccines (Infanrix versus Pediacel) with or without pneumococcal vaccination (Prevenar)

### Completion date

01/08/2007

# **Eligibility**

### Key inclusion criteria

1. Infants in good general health eligible for the fourth DTP IPV-Hib vaccination

### Participant type(s)

Patient

### Healthy volunteers allowed

No

### Age group

Child

### Sex

**Not Specified** 

### Key exclusion criteria

- 1. Severe acute illness or fever (greater than 38.5°C) within two days before vaccination
- 2. Present evidence of serious disease(s) demanding medical treatment that might interfere with the results of the study
- 3. Known or suspected allergy to any of the vaccine components
- 4. Known or suspected immune disorder
- 5. History of any neurological disorder, including epilepsy

- 6. Previous administration of plasma products (including immunoglobulins)
- 7. Previous vaccination with any other vaccine than those used in the National Immunisation Programme

### Date of first enrolment

03/11/2004

### Date of final enrolment

01/08/2007

# Locations

### Countries of recruitment

Netherlands

### Study participating centre

National Institute for Public Health and the Environment (RIVM)

Bilthoven Netherlands 3720 BA

# Sponsor information

### Organisation

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

### **ROR**

https://ror.org/01cesdt21

# Funder(s)

### Funder type

Government

### Funder Name

The Netherlands Ministry of Health, Welfare and Sport (The Netherlands)

# **Results and Publications**

Individual participant data (IPD) sharing plan

**IPD sharing plan summary**Not provided at time of registration