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

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
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

Secondary study design
Single-centre

Study setting(s)
Not specified

Study type(s)
Prevention

Participant information sheet

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
Not Specified

Drug/device/biological/vaccine name(s)
Diphtheria, Tetanus, Pertussis, Poliomyelitis - Haemophilus influenzae type b (DTP IPV-Hib) vaccine

Primary outcome measure
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).

Secondary outcome measures
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)

Overall study start date
03/11/2004

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

Age group
Child

Sex
Not Specified

Target number of participants
400

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)
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Sponsor information

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Sponsor type
Government

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https://ror.org/01cesdt21

Funder(s)

Funder type
Government

Funder Name
The Netherlands Ministry of Health, Welfare and Sport (The 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