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.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22816

Source
Nationaal Trial Register

Brief title
aKwK trial

Health condition

Infectious Diseases, Whooping Cough, Pertussis, Infectieziekten, Kinkhoest

Sponsors and support

Primary sponsor: National Institute for Public Health and the Environment (RIVM)
Source(s) of monetary or material Support: The Netherlands Ministry of Health, Welfare and Sport

Intervention

Outcome measures

Primary outcome

To compare the immunogenicity of the whole cell versus the acellular pertussis component of the DTP IPV-Hib vaccine as measured by the antibody titers at 11 months before the 4th vaccination and at 12 months. The antibody titers are determined by a twofold serial dilution ELISA.

Secondary outcome

Antibody titers for all vaccine components are measured at 11 months before vaccination and at 4-8 weeks after the 4th 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).

Study description

Background summary

This study is undertaken to monitor the effects of the changes in the pertussis component of the DTP IPV-Hib vaccine as used in the Dutch National Immunisation Programme. There are 4 study groups consisting of 11 month old children who receive the DTp IPV-Hib vaccine with different pertussis components; a whole cell, 3 component acellular, 5 component acellular and a 5 component acellular with concurrent pneumococcal vaccination. The antibody respons is measured before vaccination at 11 months old and 4-8 weeks after vaccination by ELISAs.

Study objective

To compare the immunogenicity of the whole cell versus the acellular pertussis component of the DTP IPV-Hib vaccine as measured by the antibody titers at 11 months before the 4th vaccination and at 12 months.

Study design

N/A

Intervention

4 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).

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Eligibility criteria

Inclusion criteria

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

Exclusion criteria

1. Severe acute illness or fever (>38.5) 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.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	03-11-2004
Enrollment:	400
Type:	Actual

Ethics review

Positive opinion

Date:	04-04-2007
Application type:	First submission

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
NTR-new	NL922
NTR-old	NTR946
Other	: LTR134
ISRCTN	ISRCTN97785537

Study results