A randomised controlled study with whole-cell or acellular pertussis vaccines in combination with regular DT-IPV vaccine and a new poliomyelitis (IPV-Vero) component in children 4 years of age in the Netherlands.

No registrations found.

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

Summary

ID

NL-OMON25000

Source
NTR

Brief title
Apeldoorn studie

Health condition

Infectious diseases, whooping cough, Bordetella pertussis.

Sponsors and support

Primary sponsor: National Institute of Public Health and the Environment
Source(s) of monetary or material Support: Netherlands Chief Inspectorate of Health Care

Intervention

Outcome measures

Primary outcome

To compare the immunogenicity of the whole cell versus the acellular pertussis vaccine components as measured by the antibody titers at the 3 time points. The antibody levels are determined by a twofold serial dilution ELISA.

Secondary outcome

The occurrence of adverse events after the administration of the different pertussis vaccines as recorded by the parents (non-blinded). Antibody titers directed against all other vaccine components are measured.

Study description

Background summary

In this study the immunogenicity of the whole cell pertussis vaccine and 3 acellular pertussis vaccines is compared after administration as a booster in children 4 years of age. The occurence of adverse events within 1 week after vaccination and the persistence of antibody levels after 2 years are also investigated.

After vaccination with the ACV’s almost all the titers are high against the different pertussis components and generally reflect the composition of these components present in the vaccines. The titers are comparable with those observed in other trials with these vaccines. After vaccination with the WCV the antibody levels are lower as found for the ACV's and more diverse, varying from good to low for the different pertussis vaccine antigens. A drawback of the WCV is the rate of adverse events which is in general 4 times as much as observed for the ACV's, although the adverse reactions are mostly mild and of limited duration. 2 Years after the booster vaccination almost all pertussis antibody titers have decreased to background level.

Study objective

To compare the immunogenicity of the Dutch whole cell vaccine versus 3 acellular pertussis vaccines administered as a booster at 4 years of age by measuring the antibody levels in serum after 1 month and 2 years.

Study design

Blood samples were taken just before the vaccination, 4-6 weeks and 2 years postvaccination.

Intervention

A total of 180 children 4 years of age were divided over 5 groups.

1. DT-IPV vaccine administration as controlgroup (N=45)

2. DTwP-IPV (N=44)

3. DT-IPV and aP from SKB (N=44)

4. DT-IPV and aP from Wyeth-Lederle (N=23)

5 DT-IPV and aP from Pasteur-Merieux (N=24).

Blood samples were taken just before the vaccination, 4-6 weeks and 2 years postvaccination.

Contacts

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Eligibility criteria

Inclusion criteria

1. Children in good general health eligible for the DT-IPV vaccination at 4 years of age

2. Written informed consent (IC) from parents

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:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-03-1998
Enrollment:	180
Type:	Actual

Ethics review

Positive opinion

Date:	14-08-2008
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	NL1346
NTR-old	NTR1406
Other	: LVO66A, LVO121A
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
GAM Berbers et al. RIVM report 105000 001, Jan. 1999