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.

Gepubliceerd: 14-08-2008 Laatst bijgewerkt: 18-08-2022

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.

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON25000

Bron
NTR

Verkorte titel
Apeldoorn studie

Aandoening

Infectious diseases, whooping cough, Bordetella pertussis.

Ondersteuning

Primaire sponsor: National Institute of Public Health and the Environment
Overige ondersteuning: Netherlands Chief Inspectorate of Health Care

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

RIVM, afd. LIS
Postbus 1
G. Berbers
Bilthoven 3720 BA
The Netherlands
+31 30-2742496

Wetenschappelijk

RIVM, afd. LIS
Postbus 1
G. Berbers
Bilthoven 3720 BA
The Netherlands
+31 30-2742496

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

2. Written informed consent (IC) from parents

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-03-1998
Aantal proefpersonen:	180
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	14-08-2008
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL1346
NTR-old	NTR1406
Ander register	: LVO66A, LVO121A
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten
GAM Berbers et al. RIVM report 105000 001, Jan. 1999