high immune responses after the 5th acellulair pertussis vaccination administered to 4 year old Dutch children and its relation with adverse reactions after the booster

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The elucidation of T-cell immune responses as well as IgE and IgG subclass antibody responses in children reporting severe local side effects after the fifth ACV vaccination as a component of the DTP-IPV combination vaccine. These responses will be...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON35976

Source
ToetsingOnline

Brief title
high T-cell responses in children after pertussis vaccinations

Condition

- Other condition
- Bacterial infectious disorders

Synonym
atopy, overreaction

Health condition

vaccinatie en relatie met overreaktie van het immuunsysteem, atopie

Research involving
Human

Sponsors and support

Primary sponsor: National Institute of Health
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: children, IgE, local reactions, vaccination

Outcome measures

Primary outcome

T cells will be stimulated with the various proteins of B. pertussis and both after 24 hours and 5 days of culture, cells and supernatants will be harvested. Memory Th1, Th2, Th17 and Treg cell responses will be measured by analysing cytokines in the culture supernatants by Luminex bead protein assay.

The plasma samples will be used to measure IgG subclasses, especially IgG4 as well as IgE antibody responses against the pertussis vaccine components

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Questionnaires will be used to assess local and systemic adverse events, together with information on the interval and durations of the symptoms. Information on the presence of atopic disorders will be collected also

Secondary outcome

Total IgG antibody responses against the DTP-IPV vaccine components: several proteins of B.pertussis (PT, PRN, FHA, FIM2/3), Diphtheria toxoid and Tetanus toxoid-specific will be measured in multiplex bead based immunoassays .

Total IgE and antibody titers in all samples will be measured.

HLA types of lymphocytes will be determined by DNA analysis, if parents agreed to participate on this specific point, to find out whether the incidence of sever local side-effects is related to specific HLA types of the immune system,

T-cell responses against the other proteins of the DTP-IPV vaccine will be measured if possible

Study description

Background summary

Since the acellular vaccines (ACV) for infants against whooping cough (pertussis) is introduced in the Netherlands in 2005, qualitative differences in T-cell immunity to ACV and the whole cell vaccine (WCV) have been described. Moreover, high T-cell immune responses against pertussis after ACV vaccinations have been associated with adverse events after vaccination. Vaccines are first administered at an age when the immune system is not yet fully developed and the (long term) effects of changes in the vaccination program are largely unknown. This study aims to investigate whether there is a direct correlation with T-cell immune responses after the high-dose ACV vaccinations at infant age and the severe local side effects after the fifth consecutive ACV preschool booster vaccination at 4 years of age.

Study objective

The elucidation of T-cell immune responses as well as IgE and IgG subclass antibody responses in children reporting severe local side effects after the fifth ACV vaccination as a component of the DTP-IPV combination vaccine. These responses will be compared with those in children without reporting any adverse reactions or with those children having only mild local reactions after vaccination. The Th1, Th2, Th17 and regulatory T-cell cytokine repertoires and IgG subclasses as well as IgE antibody levels against the two most important components present in the pertussis vaccines will be studied.

Study design

Case control study:
After reporting local side effects due to the boostervacination at 4 years of age, participants are being asked for blood sampling. One blood sample around 10 days after booster vaccination and questionnaires concerning adverse events and atopic diseases will be taken.

Study burden and risks

Venapuctures have not been associated with real risks

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

Cases:

One group of 4 years old children with a local reaction (swelling and/or redness) of more than 5 cm within 48 hrs after the booster vaccination with (Infanrix-IPV).
Controls:
4 years old children without any local reaction (swelling and/or redness) of less than 1 cm within 48 hrs after the booster vaccination with (Infanrix-IPV). ;Controls:
within 48 hrs after the booster vaccination with ACV (Infanrix-IPV)

Exclusion criteria

•evidence of serious disease(s) demanding immunosuppressive medical treatment, like corticosteroids within the last 3 months, that might interfere with the results of the study
•any known primary or secondary immunodeficiency
•vaccination with any other vaccine than those used in the NIP within a month before the blood sampling

Study design

Design

Study type:	Observational invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-01-2012
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO

Date:	13-10-2011
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	21-06-2012
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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
ISRCTN	ISRCTN65428640
CCMO	NL37373.100.11