Serologic evaluation of Hepatitis B vaccination (Infanrix hexa)

Published: 27-11-2007
Last updated: 08-05-2024

The aim of the study is to evaluate whether the HBV serological response to Infanrix hexa vaccination, after administration according to the Dutch National Immunisation Programme, is sufficient according to World Health Organisation (WHO) standrads...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Hepatobiliary neoplasms malignant and unspecified
Study type	Observational invasive

Summary

ID

NL-OMON31015

Source
ToetsingOnline

Brief title
Infanrix hexa evaluation

Condition

- Hepatobiliary neoplasms malignant and unspecified

Synonym
immunological response antibodies

Research involving
Human

Sponsors and support

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

Intervention

Keyword: evaluation, hepatitis B, immunerespons, vaccination

Outcome measures

Primary outcome

- proportion of participants with a anti-Hbs titer< 10IU/ml

- GMT anti-HBs titer

Secondary outcome

- anti-Hib, pneumococcen, pertussis titers

- response with regard to questions regarding acceptability of HBV vaccination

Study description

Background summary

Since 1st March 2003, hepatitis B virus (HBV) vaccine is offered in the Dutch National Immunisation Programme to children with one or two parents born in a HBV endemic country (this is about 18% of each birth cohort). Initially, HBV vaccine was offered as a separate injection. . Since 1st April 2006 it is offered as a combination vaccine (Infanrix hexa), so that pneumococcal vaccine could be introduced without increasing the number of injections to three.

There is some information in the literature, that giving pneumococcal vaccination at the same time could reduce the immunogenicity of the HBV vaccination (Scheifele, Vaccine 2006, Tichmann-Schumann, PIDJ 2005, Knuf et al., Vaccine 2006). A reduced immune response was the reason that the European Agency for the Evaluation of Medicinal Products (EMEA) withdrew the license for a vaccine that is very similar to Infanrix hexa (Hexavac; EMEA 297369/2005).

It has also been suggested that the Hib response after Infanrix vaccination could be reduced as a result of giving pneumococcal vaccine at the same time (Goldblatt, PIDJ, in press). Also the pertussis and pneumococcal response may be reduced following combined administration.

To assess the immune response is important, since an insufficient response would mean that children in the target group for HBV vaccination are insufficiently protected.

The director of the Centre for Infectious Disease control suggested that changes in the immunisation programme should be carefully evaluated, including serological evaluation. In addition, the Dutch Health Council advised in 2003 after recommending introduction of HBV vaccination for the target group, that this should be evaluated after three years.

Study objective

The aim of the study is to evaluate whether the HBV serological response to Infanrix hexa vaccination, after administration according to the Dutch National Immunisation Programme, is sufficient according to World Health Organisation (WHO) standrads.

Additional objectives are
- to assess whether the responses to the Hib, pertussis and pneumococcal components are sufficient after combined administration of Infanrix hexa and pneumococcal vaccine.
- To assess the acceptability of HBV vaccination.

Study design

The serological evaluation will be carried out using similar methods as are currently employed for the serological evaluation of children of HBV carrier mothers. Parents of eligible children will be invited at the child health clinic (consultatiebureau) to take part. When agreeing to take part, they are asked to bring their child to a clinic, 4 to 6 weeks after the last (fourth) Infanrix hexa vaccination, so that blood can be taken through venapuncture. Travel costs will be reimbursed (participants receive a 'strippenkaart'). Blood will be sent to RIVM, with subsequent serological tests carried out at UMCU (anti-Hbs, HBsag) and at RIVM (other serological tests). HBsAg will only be determined for children with a anti-HBs titer <100 IU/ml.

The serological tests regarding the additional study questions (Hib, pertussis and pneumococcal disease) will be carried out once funding is available. Hence, the results of these tests will not be communicated with participants' parents.

Results re HBV will be sent to the participant's child health clinic. In case of a sufficient serological response, the results will also be sent directly to the parents. In case of insufficient response, the results will be communicated trhough the child health clinic. Then, a new series of vaccinations will be offered, with a subsequent serological test. In case of HBV carriage, this will be communicated with the parents during a child health clinic visit. In this case, the general practitioner will also be informed, with the advice to refer the child to a specialist.

To assess acceptability, questions regarding the HBV vaccination and other

vaccinations will be asked in questionnaire, to parents of participants.

Study burden and risks

Participants will be asked to give blood once (through venapuncture). When the HBV response is insufficient, additional HBV vaccinations with a subsequent new serological evaluation, will be offered.

Contacts

Public
RIVM

Antonie van Leeuwenhoeklaan 9
3721 MA BILTHOVEN
Nederland
Scientific
RIVM

Antonie van Leeuwenhoeklaan 9
3721 MA BILTHOVEN
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

Children vaccinated with the combination vaccin Infanrix hexa, of which hepatitis B is a part

Exclusion criteria

Children not vaccinated with the combination vaccine Infanrix hexa and children born to women with hepatitis B infection will be excluded.

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	10-05-2009
Enrollment:	300
Type:	Actual

Ethics review

Approved WMO

Date:	27-11-2007
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

Approved WMO

Date:	27-01-2009
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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
CCMO	NL18701.041.07