Effect of 2 versus 3 pneumococcal conjugate vaccinations Prevnar on nasopharyngeal carriage, transmission and herd immunity;a randomized, controlled study.

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Two vaccinations before the age of 6 months with the pneumococcal conjugate vaccine Prevnar in infants will protect the children against invasive pneumococcal disease. Two vaccinations at 2 and 4 months of age without a booster vaccination at 11…

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

Samenvatting

ID

NL-OMON26724

Bron
NTR

Verkorte titel
MINOES

Aandoening

Prevention of invasive pneumococcal disease in healthy infants

Ondersteuning

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Overige ondersteuning: Netherlands Ministry of Health, Welfare and Sport

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Pneumococcal nasopharyngeal carriage before 2 months of age, and at 6, 12, 18 and 24 months of age in vaccinated children (groups I and II) and controls (group III), and NP pneumococcal carriage of siblings and parents/caregivers when the baby is 12 and 24 months of age (herd immunity).

Toelichting onderzoek

Achtergrond van het onderzoek

Two vaccinations with the pneumococcal conjugate vaccine Prevnar in infants provide over 90% protection against invasive pneumococcal disease (IPD) for those pneumococcal serotypes included in the vaccine.
Licensure of the vaccine however is based on studies in which infants received 3 vaccinations before the age of 6 months with a fourth booster vaccination after 6 months (3+ 1 scheme). Vaccinations result in a 50% reduction of nasopharyngeal (NP) pneumococcal colonization of those serotypes included in the vaccine.
In the USA, substantial herd-immunity has been reported for unvaccinated individuals as well due to the reduced carriage of NP vaccine-types in vaccinated infants who are a primary source of spreading pneumococci in the community. The overall pneumococcal colonization in infants however was not reduced after conjugate pneumococcal vaccinations because of a similar increase in carriage of non-vaccine pneumococal serotypes. The increase of the replacing pneumococci in diseases like otitis media and invasive pneumococcal disease has been reported. Furthermore, the NP carriage reduction of vaccine-type pneumococci seems to influence the presence of other potentially pathogenic bacterial species. Active post-marketing surveillance after the general introduction of pneumococcal vaccines is therefore advised.

While a 2-doses vaccination scheme without booster vaccination may offer sufficient protection against IPD, it may lead to less carriage reduction of vaccine-type pneumococci and therefore less replacement by non-vaccine pneumococci and other potential pathogenic bacteria which perhaps may be a major advantage. Although less herd-immunity and less

influence on respiratory tract infections may occur, ongoing natural boosting of immunity by frequent colonization of vaccine serotypes may result in long-term persistence of protective antipneumococcal serum antibody levels both in infants and the community.
Apart from cost-effectiveness, the reduction of the number of pneumococcal vaccinations in the infant vaccination program therefore may have major advantages.

The primary aim of the present study is to compare the influence of 2 vaccinations (2 and 4 months of age) and 2+1 vaccinations (booster vaccination at 11 months) on nasopharyngeal pneumococcal colonization both in infants and in parents and siblings.
Nasopharyngeal swabs will be obtained before 2 months and at 6, 12, 18 and 24 months of age from the children and from one parent/caregiver and one sibling at 12 and 24 months of age.
Secundairy aim is to determine long-term serum antipneumococcl antibody levels after 2 and 2+ 1 vaccinations at the age of 12 and 24 months of the children.
Further opportunities of this study are determination of (vaccine and non-vaccine serotypes) colonization of unvaccinated infants before introduction of Prevnar in the Dutch National Vaccination Program, evaluation of replacing pneumococcal serotypes after Prevnar vaccinations and investigation of the influence of Prevnar on other colonizing bacterial species. The relation between invasive pneumococcal disease and pneumococcal colonization in the Netherlands and the potential reduction of physician-diagnosed acute otitis media and lower respiratory tract infections after pneumococcal conjugate vaccinations will be evaluated.
The study will include 333 newborns and family members in each of the 3 intervention groups; group I Prevnar at 2 and 4 months, group II at 2, 4 and 11 months and group III at 24 months of age (controls). Children and families will be followed for 2 years. The study has started in June 2005.

Doel van het onderzoek

Two vaccinations before the age of 6 months with the pneumococcal conjugate vaccine Prevnar in infants will protect the children against invasive pneumococcal disease.
Two vaccinations at 2 and 4 months of age without a booster vaccination at 11 months will have less effect on vaccine-type pneumococcal carriage reduction and therefore also herd-immunity and respiratory tract infections but also less pneumococcal replacement by non-vaccine types and other potentially pathogenic bacteria.

Onderzoeksproduct en/of interventie

Three groups of each 333 newborns

Group I: Prevnar at age 2 and 4 months;

Group II: Prevnar at age 2, 4 and 11 months;

Group III: Prevnar at age 24 months.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1000 healthy newborns (and family members) who will receive childhood vaccinations according to the national vaccination program, starting at 2 months of age.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Exclusion from the national vaccination program because of the presence of a medical

condition requiring treatment that can interfere with the results of vaccinations,
known of suspected allergy to components of the vaccine,
known or suspected immunodeficiency disease other than IgA or IgG-subclass deficiency,
previous treatment with plasma or immunoglobulins,
previous vaccinations other than hepatitis B vaccinations,
coagulations disorders.

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	20-06-2005
Aantal proefpersonen:	1000
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	20-08-2005
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	NL122
NTR-old	NTR155
Ander register	: MINOES 01, STEG R05 008
ISRCTN	ISRCTN25571720

Resultaten

Samenvatting resultaten
N/A