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

Submission date
20/12/2005

Registration date
20/12/2005

Last Edited
31/05/2019

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.onderzoekminoes.nl

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
NCT00189020

Secondary identifying numbers
MINOES 01, STEG R05 008

Study information

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

Acronym
MINOES

Study objectives
Study hypotheses amended as of 22/05/2007:
1. Two vaccinations with 7-valent conjugate vaccine before six months of age will protect against invasive pneumococcal disease in the first 18 to 24 months of life
2. 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
3. Anti-pneumococcal antibody development after two vacinations with 7-valent conjugate vacine before six months of age and revaccination at 24 months of age will be equal or better compared with antibody development after two vaccination before six months of age followed by booster vaccination at 11 and 24 months of age. Later vaccination will improve long term protection

Previous study hypothesis:
1. Two vaccinations before the age of 6 months with the pneumococcal conjugate vaccine Prevnar in infants will protect the children against invasive pneumococcal disease.
2. 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.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approval received from the local medical ethics board (Stichting Therapeutische Evaluatie Geneesmiddelen [STEG], acknowledged by the Centrale Commissie Mensgebonden Onderzoek [CCMO], The Netherlands) on the 21st June 2005 (ref: STEG R05.008, version 6).

First and second amendment (collection of saliva for immunological analysis and extension microbiology research of collected nasopharyngeal swabs in subgroups of children) approved on the 11th September 2006.

Third amendment (addition of booster vaccination at 24 months and blood sampling) approved on the 2nd March 2007 (ref: STEG R05-008, MINOES version 8 dd february 2007).

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

Participant information sheet

Health condition(s) or problem(s) studied
Invasive pneumococcal disease, Respiratory tract infection.

Added as of 22/05/2007:
Change in: nasopharyngeal carriage after reduced doses 7-valent conjugate vaccine, antipneumococcal antibody development, family transmission of pneumococci

Interventions
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

Amendment made as of 22/05/2007:
Groups I and II will receive booster vaccination 7-valent conjugate vaccine at 24 months of age.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Pneumococcal conjugate vaccine Prevnar

Primary outcome measure

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).

Secondary outcome measures
1. Determination of pneumococcal (vaccine and non-vaccine serotypes) colonization of infants in the Netherlands before introduction of Prevnar in the National Vaccination Program (group III)
2. Evaluation of replacing pneumococcal serotypes after Prevnar vaccinations
3. Influence of Prevnar vaccinations on other colonizing bacterial species like Staphylococcus, H. influenzae, M. catarrhalis and Streptococcus
4. Anti pneumococcal antibody levels at 12 and 24 months after 2 doses as compared to 2+1 Prevnar vaccinations
5. Relation between invasive pneumococcal disease and pneumococcal colonization in the Netherlands
6. Evaluation of potential reduction of physician-diagnosed acute otitis media and lower respiratory tract infections after pneumococcal conjugate vaccinations

Added as of 22/05/2007:
7. Comparison of anti-pneumococcal antibody levels after vaccinations at 2, 4 and 24 months, at 2, 4, 11 and 24 months and after primo-vaccination at 24 months of age in subgroups of 80 children of groups I, II and III
8. Comparison of B-memory cells after vaccination at 24 months of age after vaccination schemes of groups I, II and III

Overall study start date
20/06/2005

Completion date
01/03/2008

Eligibility

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

Participant type(s)
Patient

Age group
Neonate

Sex
Both

Target number of participants
1000

Total final enrolment

1003

Key exclusion criteria
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

Date of first enrolment
20/06/2005

Date of final enrolment
01/03/2008

Locations

Countries of recruitment
Netherlands

Study participating centre
University Medical Center Utrecht
Utrecht
Netherlands
3508 AB

Sponsor information

Organisation
University Medical Centre Utrecht (UMCU) (Netherlands)

Sponsor details
PO Box 85500
Utrecht
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3508 GA

Sponsor type
University/education

Website
http://www.umcutrecht.nl/zorg/

ROR
https://ror.org/04pp8hn57

Funder(s)

Funder type
Government

Funder Name
The Netherlands Ministry of Health, Welfare and Sport (The Netherlands)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/09/2011	31/05/2019	Yes	No
Results article	results	01/12/2014	31/05/2019	Yes	No
Results article	results	01/08/2014	31/05/2019	Yes	No
Results article	results	02/12/2013	31/05/2019	Yes	No
Results article	results	01/12/2011	31/05/2019	Yes	No
Results article	results	01/02/2014	31/05/2019	Yes	No
Results article	results	08/07/2009	31/05/2019	Yes	No
Results article	results	08/09/2010	31/05/2019	Yes	No