A study comparing the effect of various schedules of the 7-valent licensed CRM197 - conjugated pneumococcal vaccine (Prevnar®) on carriage of Streptococcus pneumoniae in infants and toddlers

Submission date	Recruitment status No longer recruiting	Prospectively registered		
04/07/2005		☐ Protocol		
Registration date	Overall study status Completed Condition category	Statistical analysis plan		
01/09/2005		[X] Results		
Last Edited		Individual participant data		
14/04/2010	Infections and Infestations			

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

0887X-101801

Study information

Scientific Title

Study objectives

Number of doses of Prevnar and age of administrration will affect pneumococcal carriage

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Prevention

Participant information sheet

Health condition(s) or problem(s) studied

Healthy children

Interventions

Group A-D will be randomized using a random number table

- 1. Group A (n = 175) will receive the vaccine at 2, 4, 6 and 12 months (The 'Classical' Group)
- 2. Group B (n = 175) will receive the vaccine at 2, 4, and 6 months, but no booster will be given at 12 months. A booster dose will be offered at age 30 months, at the end of the follow-up.
- 3. Group C (n = 175) will receive the vaccination at 4, 6, 12 months. No dose at 2 months.
- 4. Group D (n = 175) will receive the vaccine at 12 and 18 months. This will be the main intervention group.
- 5. Group E (n = 30) will receive only 1 dose of PCV7 to document immunogenicity after one dose given at 18 months of age for comparison with group D when PCV7 will be given at 12 and 18 months, so that the effect of booster at 18 months versus the effect of age maturation will

be tested.

6. Group F - These are the unvaccinated controls. We have been looking for S. pneumoniae carriage in the various age groups in our populations in the last several years. So far, we collected over 1,200 nasopharyngeal (NP) cultures from healthy children in the community in the last 2.5 years. The carriage rate was similar in the various years, with no remarkable year-to-year variations.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

7-valent licensed CRM197 - conjugated pneumococcal vaccine (Prevnar®)

Primary outcome measure

Pneumococcal carriage of Vaccine-type serotypes

Secondary outcome measures

Correlates between carriage and post vaccination antibodies

Overall study start date

21/07/2005

Completion date

31/07/2008

Eligibility

Key inclusion criteria

1. Age:

Groups A, B, C, D: 2 m +/- 3 weeks

Group E: 18 m +/- 1 m

- 2. Males or females
- 3. On time for routine immunization
- 4. For group E: Received previously 4 doses of Diphtheria, Tetanus, Pertussis (DTP), Haemophilus influenzae type b (Hib) and inactivated polio vaccine (IPV)
- 5. The parents and legal guardians must understand and be able, willing and likely to fully comply with the study procedures and restrictions
- 6. The parents and legal quardians must provide written informed consent
- 7. Patient must be healthy during vaccination procedure

Participant type(s)

Patient

Age group

Child

Lower age limit

2 Months

Sex

Both

Target number of participants

730

Kev exclusion criteria

- 1. Prematurity of less than 35 weeks
- 2. Acute disease at the time of enrollment. Acute disease is defined as the presence of a moderate or severe illness with or without a fever. Study vaccines can be administered to persons with a minor illness such as diarrhea or mild upper respiratory infection (URI) without fever (rectal temperature <38.0 °C/100.4 °F).
- 3. Axillary temperature >38.0 °C/100.4 °F prior to any injection
- 4. Any clinically important congenital abnormality, any inherited disorder of the metabolism
- 5. Thrombocytonpenia or any coagulation disorder that would contraindicate intramuscular (im) injection
- 6. Prior receipt of a licensed or investigational pneumococcal vaccine
- 7. Chronic (defined as more than 14 consecutive days) use of immunosuppressants or other immune-modifying drugs. For corticosteroids, this is defined as daily systemic therapy with prednisone or its equivalent at a dose of ≥2 mg/day.
- 8. Known or suspected allergy to any constituent of either product administered in the study
- 9. Known or suspected intolerance of hypersensitivity, to the study materials (or closely related compounds) or any of the stated ingredients, including diphtheria toxoid and tetanus toxoid
- 10. Hypotonic-hyporesponsive state within 48 hours after a prior dose of any vaccine
- 11. Persistent inconsolable crying lasting ≥3 hours within 48 hours after a prior dose of any vaccine
- 12. Known to be infected with human immunodeficiency virus (HIV) or mother is HIV positive
- 13. Any other condition or social circumstance (e.g. lack of a telephone, impending relocation) that, in the opinion of the investigator, would make the subject unsuitable or unable to complete the study

Date of first enrolment

21/07/2005

Date of final enrolment

31/07/2008

Locations

Countries of recruitment

Israel

Study participating centre
Pediatric Infectious Disease Unit

Beer-Sheva Israel 84101

Sponsor information

Organisation

Individual Sponsor (Israel)

Sponsor details

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Sponsor type

Not defined

Funder(s)

Funder type

Industry

Funder Name

Wyeth Pharmaceuticals Ltd

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	15/05/2010		Yes	No