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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Study type(s)
Prevention

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(s)
Pneumococcal carriage of Vaccine-type serotypes

Key secondary outcome(s))
Correlates between carriage and post vaccination antibodies

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 guardians must provide written informed consent
7. Patient must be healthy during vaccination procedure

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
2 months

Sex
All

Key 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)

Funder(s)

Funder type
Industry

Funder Name
Wyeth Pharmaceuticals Ltd

Results and Publications

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