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A phase II/III, observer-blind, randomised, active controlled study to compare the safety and immunogenicity of a meningococcal A conjugate vaccine (PsA-TT) with meningococcal ACWY polysaccharide vaccine administered in healthy children 2 to 10 years of age

Submission date
14/08/2007

Registration date
14/08/2007

Last Edited
01/03/2019

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Infections and Infestations

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

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
RPC219; PsA-TT-003a

Study information

Scientific Title
A phase II/III, observer-blind, randomised, active controlled study to compare the safety and immunogenicity of a meningococcal A conjugate vaccine (PsA-TT) with meningococcal ACWY polysaccharide vaccine administered in healthy children 2 to 10 years of age

Study objectives
Bacterial meningitis is a life-threatening medical emergency. Morbidity includes hearing loss, chronic seizures, and learning disability. The principal pathogens of bacterial meningitis are Neisseria meningitidis, Streptococcus pneumoniae and Haemophilus influenzae type B. Neisseria meningitidis is particularly feared because it has the capability of causing large outbreaks of disease. Endemic meningococcal disease occurs worldwide and is mostly caused by meningococci of serogroups A, B, C, W135 and Y.

Hypothesis:
To compare the immunogenicity of a single dose of the PsA-TT vaccine with that of the Meningococcal A component of the PsACWY vaccine at 28 days after vaccination.

Ethics approval required
Old ethics approval format

Ethics approval(s)
King Edward Memorial Hospital Ethics Committee, Pune, India, 01/08/2007

Primary study design
Interventional

Study design
Phase II/III observer-blind randomised active-controlled study

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Bacterial meningitis

Interventions
1. One 0.5 ml dose out of a decadose vial of PsA-TT vaccine will be injected intramuscularly (IM) in the right deltoid
2. One 0.5 ml dose of PsACWY vaccine will be injected IM in the right deltoid

Intervention Type
Biological/Vaccine

Phase
Phase II/III

Drug/device/biological/vaccine name(s)
PsA-TT, PsACWY

Primary outcome(s)
The percentage of subjects who show a seroconversion for anti-Meningococcal Polysaccharide A (MenPsA) antibodies, i.e., a four-fold increase in post-immunisation serum titre with respect to pre-immunisation serum titre, at 28 days after a single vaccine dose, as measured by a rabbit complement Serum Bactericidal Assay (rSBA).

Key secondary outcome(s)
Safety:
1. The percentage of subjects with local and systemic post-immunisation reactions during the first four days, adverse events and Serious Adverse Events (SAEs), as measured at 4 and 28 days after vaccination (reactogenicity and short-term safety)
2. The percentage of subjects with SAEs during the entire study duration, as measured at 182 days (6 months) and 364 days (1 year) (long-term safety)

Immunogenicity:
1. The percentage of subjects with anti-MenPsA titre greater than or equal to 1:8 (defined as seroprotection to MenA) at 28 days after a single vaccine dose, as measured by rSBA assay. The percentage of subjects with anti-MenPsA titer greater than or equal to 1:128 (defined as long-term seroprotection to MenA) will be also considered
2. Geometric Mean Titres (GMTs) for anti-MenPsA antibodies at 28 days after a single vaccine dose, as measured by rSBA assay
3. Evaluation of reverse cumulative distribution curves for MenPsA antibody titres at 28 days after a single vaccine dose, as measured by rSBA assay
4. The percentage of subjects who show a seroconversion for anti-MenPsA total Immunoglobulin G (IgG), i.e. a two-fold increase in post-immunisation serum concentration with respect to pre-immunisation serum concentration, at 28 days after a single vaccine dose, as measured by Enzyme-Linked Immunosorbent Assay (ELISA). The percentage of subjects with a four-fold increase in post-immunisation serum concentration with respect to pre-immunisation serum concentration will be also considered

Completion date
20/11/2007

Eligibility

Key inclusion criteria
1. Age 2 to 10 years of age (both included)
2. Written informed consent obtained from parents or legal guardian of the child
3. Free of obvious health problems as established by medical history including physical examination and clinical judgment of the investigator
4. Parents or legal guardian capable and willing to bring their child or to receive home visits (for their child) for all follow-up visits
5. Residence in the study area
6. Fully vaccinated according to the local Expanded Program on Immunisation (EPI) schedule

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
2 Years

Upper age limit
10 Years

Sex
All

Key exclusion criteria
1. Previous vaccination against Neisseria meningitidis
2. Known exposure to Neisseria meningitidis during the three previous months
3. History of allergic disease or known hypersensitivity to any component of the two study vaccines and/or following administration of vaccines included in the local program of immunisation
4. Administration of any other vaccine within 60 days prior to administration of study vaccines or planned vaccination during the first 28 days after the study vaccination
5. Use of any investigational or non-registered drug within 90 days prior to the administration of study vaccines
6. Administration of immunoglobulins and/or any blood products within 30 days prior to the administration of study vaccines or planned administration during the study period
7. Chronic administration (defined as more than 14 days) of immunosuppressants or other immune-modifying agents within 90 days prior to the administration of study vaccines (including systemic or inhaled corticosteroids, this means prednisone, or equivalent, greater than 0.5 mg/kg /day; topical steroids are allowed)
8. A family history of congenital or hereditary immunodeficiency
9. History of meningitis or seizures or any neurological disorder
10. Major congenital defects or serious chronic illness, including malnutrition (as per investigator's judgment)

11. Acute disease at the time of enrolment (acute disease is defined as the presence of a moderate or severe illness with or without fever) is a temporary exclusion
12. Acute or chronic, clinically significant pulmonary, cardiovascular, hepatic, or renal functional abnormality, as determined by medical history, physical examination or laboratory tests, which in the opinion of the investigator, might interfere with the study objectives
13. Any condition or criteria that in the opinion of the investigator might compromise the well being of the subject or the compliance with study procedures or interfere with the outcome of the study
14. Non residence in the study area or intent to move out within one year

Date of first enrolment
20/08/2007

Date of final enrolment
20/11/2007

Locations

Countries of recruitment
India

Switzerland

Study participating centre
Initiative for Vaccine Research
Geneva
Switzerland
CH-1211

Sponsor information

Organisation
Serum Institute of India Limited (SIIL)

Organisation
Program for Appropriate Technology in Health (PATH)

Organisation
Serum Institute of India (India)

ROR

https://ror.org/04jk2xb11

Funder(s)

Funder type
Charity

Funder Name
Bill and Melinda Gates Foundation

Alternative Name(s)
Bill & Melinda Gates Foundation, Gates Foundation, Gates Learning Foundation, William H. Gates Foundation, BMGF, B&MGF, GF

Funding Body Type
Government organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United States of America

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	15/11/2015		Yes	No
Results article	results	15/11/2015		Yes	No
Results article	results	15/11/2015		Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes