

A phase II, observer-blind, randomised, active controlled study to compare the safety, immunogenicity, and induction of immunological memory of a meningococcal A conjugate vaccine, a meningococcal ACYW polysaccharide vaccine and a hib conjugate vaccine, administered in healthy toddlers 12 - 23 months of age

Submission date

20/09/2006

Recruitment status

No longer recruiting

Prospectively registered

Protocol

Registration date

21/09/2006

Overall study status

Completed

Statistical analysis plan

Results

Last Edited

05/03/2019

Condition category

Infections and Infestations

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

RPC178

Study information

Scientific Title

A phase II, observer-blind, randomised, active controlled study to compare the safety, immunogenicity, and induction of immunological memory of a meningococcal A conjugate vaccine, a meningococcal ACYW polysaccharide vaccine and a hib conjugate vaccine, administered in healthy toddlers 12 - 23 months of age

Study objectives

The present study is pivotal, designed as a non-inferiority trial to evaluate the immunogenicity and the safety of one dose of 10 µg of PsA-TT vaccine. Immunological memory and persistence of antibodies induced by a single intramuscular injection of the study vaccine will also be evaluated. The immunogenicity will be assessed against that of a licensed meningococcal polysaccharide ACYW vaccine. The three-group design will allow comparison of the PsA-TT vaccine (study vaccine group) safety profile with that of two licensed vaccines: the meningococcal ACYW tetravalent polysaccharide vaccine (Mencevax - reference vaccine group), and the Hib-conjugate vaccine (Hiberix - control vaccine group). The booster study is expected to provide evidence that the PsA-TT conjugate vaccine is able to prime immunological memory. Antibody persistence will be evaluated at eight months (i.e. before the booster dose), one year and two years after the first dose.

Ethics approval required

Old ethics approval format

Ethics approval(s)

This protocol has been approved by the following institutions:

1. Human Subjects Protection Committee at PATH, USA
2. University of Maryland Baltimore Institutional Review Board (IRB), USA
3. Comité d'Ethique de la Faculté de Médecine, de Pharmacie et d'Odonto-Stomatologie, Mali
4. Medical Research Council Scientific Coordinating Committee, The Gambia
5. Medical Research Council Gambia Government Ethics Committee, The Gambia
6. World Health Organization (WHO) Research Ethics Review Committee

Study design

Phase II observer-blind randomised active-controlled study

Primary study design

Interventional

Study type(s)

Prevention

Health condition(s) or problem(s) studied

Meningococcal A disease

Interventions

The intervention is vaccination at day zero of one of the three vaccines: study vaccine, reference vaccine (Mencevax) or control vaccine (Hiberix) , followed by a booster vaccination 32 weeks later with one of the three vaccines, study vaccine, reference vaccine (1/5th of a dose) or control vaccine. Subjects will be randomised in a 1:1:1 ratio.

Intervention Type

Biological/Vaccine

Phase

Phase II

Drug/device/biological/vaccine name(s)

PsA-TT, Mencevax, Hiberix

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 rank Signaling Block Assay (rSBA) assay.

Key secondary outcome(s)

1. The percentage of subjects with local and systemic adverse events, including solicited adverse reactions and events, and Serious Adverse Events (SAEs), as measured at four and 28 days after the primary vaccination (reactogenicity and short-term safety)
2. The percentage of subjects with local and systemic adverse events, including solicited adverse

reactions and events, and SAEs, as measured at four and 28 days after the booster vaccination (reactogenicity and short-term safety)

3. 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 the 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

28/11/2008

Eligibility

Key inclusion criteria

1. Age 12 to 23 months of age (both included)
2. Written informed consent obtained from the mother, father, or 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. Mother, father, or 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 local Expanded Program on Immunisation (EPI) schedule

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Child

Lower age limit

12 months

Upper age limit

23 months

Sex

All

Key exclusion criteria

1. Previous vaccination against serogroup A Neisseria meningitidis
2. Known exposure to serogroup A Neisseria meningitidis during the three previous months
3. History of allergic disease or known hypersensitivity to any component of the three study vaccines
4. History of Serious Adverse Reactions (SAR) following administration of vaccines included in the local program of immunization
5. Administration of any other vaccine within 60 days prior to administration of study vaccines or

- planned vaccination during the first four weeks after the study vaccination
6. Use of any investigational or non-registered drug within 90 days prior to the administration of study vaccines
 7. Administration of immunoglobulins and/or any blood products since birth or planned administration during the vaccine period
 8. Chronic administration (defined as more than 14 days) of immunosuppressants or other immune-modifying agents since birth (including systemic or inhaled corticosteroids, this means prednisone or equivalent, 0.5 mg/kg/day [topical steroids are allowed])
 9. A family history of congenital or hereditary immunodeficiency
 10. History of meningitis or seizures or any neurological disorder
 11. Major congenital defects or serious chronic illness, including malnutrition (as per investigator's judgment)
 12. 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
 13. 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
 14. 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
 15. Non-residence in the study area or intent to move out within one year

Date of first enrolment

28/08/2006

Date of final enrolment

28/11/2008

Locations

Countries of recruitment

Gambia

Mali

Switzerland

Study participating centre

World Health Organization

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?
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