

A phase II, double-blind, randomised, controlled, dose ranging study to evaluate the safety, immunogenicity, dose response and schedule response of a meningococcal A conjugate vaccine administered concomitantly with local expanded program on immunisation (EPI) vaccines in healthy infants

Submission date 06/08/2008	Recruitment status No longer recruiting	☒ Prospectively registered ☐ Protocol
Registration date 06/08/2008	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 23/09/2025	Condition category Nervous System Diseases	☐ Individual participant data

Plain English summary of protocol

Background and study aims

Meningitis is an infection that causes inflammation of the meninges (the protective lining that cover the brain and spinal cord). Meningitis can be bacterial or viral, but bacterial meningitis is far more serious. If bacterial meningitis is not treated in time, then it can cause severe brain damage and infect the blood (septicaemia) leading to death. In Africa, more than 90% of meningitis epidemics are caused by a bacterial variety commonly referred to as group A meningitis, which mainly affects children. Due to the widespread devastation this disease has caused, a vaccine has been produced for use against meningitis A in sub-Saharan Africa, known as MenAfriVac. An important part in the development of new vaccines is to measure how effective they are, and how long the immunity gained from them lasts for. This information provides useful information about vaccination programmes and schedules (i.e. if "booster" injections are needed). The aim of this study is to determine the safest dose of the MenAfriVac vaccine and whether it is more effective when given alone or with the recommended vaccines for children (EPI vaccines).

Who can participate?

Healthy children aged between 14 and 18 weeks, who have received all of the recommended (EPI) vaccines for their age.

What does the study involve?

Participants are randomly allocated into four groups. The first group receive doses of MenAfriVac at 14 weeks and 9 months of age, the second group receive a dose at 9 months of

age, the third group receive a dose at 12 months of age and the fourth group only receives the recommended vaccines (EPI). After 28 days, a blood sample is taken so that the immunity against group A meningitis is measured.

What are the possible benefits and risks of participating?

There is no direct benefit of participating in the study, however if any of the children involved have any sudden illnesses, then this will be treated straight away. There are no notable risks of participating other than possible discomfort during blood tests.

Where is the study run from?

Navrongo Health Research Centre (Ghana)

When is the study starting and how long is it expected to run for?

August 2008 to December 2017

Who is funding the study?

Bill and Melinda Gates Foundation (USA)

Who is the main contact?

Dr Marie-Pierre Preziosi

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Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

RPC258, PsA-TT-004, PsA-TT 004

Study information

Scientific Title

A phase II, double-blind, randomised, controlled, dose ranging study to evaluate the safety, immunogenicity, dose response and schedule response of a meningococcal A conjugate vaccine

administered concomitantly with local expanded program on immunisation (EPI) vaccines in healthy infants

Study objectives

The aim of this Phase II dose-ranging clinical study is to evaluate the safety and immunogenicity of three different formulations of the PsA-TT vaccine (2.5, 5 or 10 µg concentration of Men A polysaccharide).

Ethics approval required

Old ethics approval format

Ethics approval(s)

1. Western Institutional Review Board, 30/11/2007, ref: 1095050)
2. Ghana Health Service Ethical Review Committee, 12/06/2008, ref: GHS-ERC 01/1/08
3. Navrongo Health Research Centre Institutional Review Board, 07/07/2008, ref: NHRCIRB070
4. Food and Drugs Board (Ghana), 25/07/2008, ref: FDB/CT/803

Study design

Phase II double-blind randomised dose-ranging controlled clinical study

Primary study design

Interventional

Study type(s)

Prevention

Health condition(s) or problem(s) studied

Bacterial meningitis

Interventions

All participants are given the Expanded Programme on Immunization (EPI) vaccines. OPV and Pentavalent DTwPHBVHib vaccines are given at 6 weeks (with completion of a 10 and 14 week schedule), a single dose of yellow fever and measles vaccine is administered at 9-12 months, and a booster of pentavalent DTwPHBVHib vaccine is given at 12-18 months. Participants are then randomly allocated into one of four groups:

Group 1: EPI vaccines concomitantly with two doses of the study vaccine (PsA-TT) in infancy at 14 weeks and 9 months of age

Group 2: EPI vaccines concomitantly with one single dose of the study vaccine (PsA-TT) in infancy at 9 months of age

Group 3: EPI vaccines concomitantly with one single dose of the study vaccine (PsA-TT) in the first year of life at 12 months of age

Group 4: EPI vaccines only

Intervention Type

Biological/Vaccine

Phase

Phase II

Drug/device/biological/vaccine name(s)

PsA-TT

Primary outcome(s)

To compare the immunogenicity at 28 days after vaccination of range dosages of the PsA-TT vaccine, when administered to infants in a two-dose schedule at 14 weeks and 9 months of age concomitantly with EPI vaccines.

Key secondary outcome(s)

1. Safety of range dosages of the PsA-TT vaccine, when administered to healthy infants in a two-dose schedule at 14 weeks and 9 months of age concomitantly with EPI vaccines (i.e. diphtheria, tetanus, whole cell pertussis, hepatitis B, Hib, and oral poliomyelitis at 14 weeks; measles and yellow fever at 9 months)
2. Immunogenicity of the EPI vaccines in all vaccines groups, when administered alone or concomitantly with the PsA-TT vaccine at 14 weeks, 9 months, and 12 months of age
3. Immunogenicity at 28 days, at 12 and 24 months (i.e. at 24 and 36 months of age) after a single dose of the PsA-TT vaccine administered at 12 months of age concomitantly with EPI vaccines

Completion date

31/12/2012

Eligibility

Key inclusion criteria

1. Aged 14 to 18 weeks old
2. Free of obvious health problems as established by medical history including physical examination and clinical judgment of the investigator
3. Guardian capable and willing to bring their child or to receive home visits for their child for all follow-up visits
4. Residence in the study area
5. Fully vaccinated according to the local EPI schedule (Bacillus Calmette-Guerin [BCG] and OPV at birth, two doses of diphtheria, tetanus, whole cell pertussis, haemophilus influenzae type B and hepatitis B virus [DTwPHibHBV] and OPV at 6 and 10 weeks of age)

Participant type(s)

Healthy volunteer

Healthy volunteers allowed

No

Age group

Child

Lower age limit

14 weeks

Upper age limit

18 weeks

Sex

All

Key exclusion criteria

1. Previous vaccination against serogroup A *Neisseria meningitidis*
2. Known exposure to serogroup A *N. meningitidis* since birth
3. History of allergic disease or known hypersensitivity to any component of the study vaccines
4. History of serious adverse reactions following administration of vaccines included in the local program of immunisation
5. Administration of any vaccine other than EPI vaccines within 30 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 since birth
7. Administration of immunoglobulins and/or any blood products since birth or planned administration during the study period
8. Chronic administration (defined as more than 14 days) of immunosuppressant or other immune-modifying agents since birth (including systemic or inhaled corticosteroids, this means prednisone, or equivalent, greater than 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). Minimum weight should be of 4 kg at the time of enrolment in the study (at 14 - 18 weeks of age).
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 2 years

Date of first enrolment

18/08/2008

Date of final enrolment

31/12/2017

Locations

Countries of recruitment

Ghana

Study participating centre

Navrongo Health Research Centre

Ghana Health Service

Navrongo

Ghana

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Sponsor information

Organisation

Serum Institute of India Limited

ROR

<https://ror.org/04jk2xb11>

Funder(s)

Funder type

Charity

Funder Name

Bill and Melinda Gates Foundation (USA)

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				

Results article		15/11/2015		Yes	No
Results article	results	15/11/2015		Yes	No
Results article	Immunogenicity and safety	17/09/2025	23/09/2025	Yes	No