ISRCTN82484612 https://doi.org/10.1186/ISRCTN82484612

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

Registration date
06/08/2008

Overall study status
Completed

Last Edited
05/03/2019

Condition category
Nervous System Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
RPC258

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

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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 measure
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.

Secondary outcome measures
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

Overall study start date
18/08/2008

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

Age group
Child

Lower age limit
14 Weeks

Upper age limit
18 Weeks

Sex
Both

Target number of participants
Initial study: 1200,

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

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Sponsor type
Research organisation

Website
http://www.seruminstitute.com

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, 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

Publication and dissemination plan
Publication of the initial study is planned by 2016.

Intention to publish date
31/12/2016

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	15/11/2015		Yes	No
Results article	results	15/11/2015		Yes	No
Results article	results	15/11/2015		Yes	No
Results article	results	15/11/2015		Yes	No