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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

Registration date
21/09/2006

Last Edited
05/03/2019

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Infections and Infestations

[_] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

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

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 measure
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 Age (rSBA) assay.

Secondary outcome measures
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 ImmunoadSorbent 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

Overall study start date
28/08/2006

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

Age group
Child

Lower age limit

12 Months

Upper age limit
23 Months

Sex
Both

Target number of participants
600

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)

Sponsor details
212/2, Hadapsar
Pune
India
411028

Sponsor type
Research organisation

Website
http://www.seruminstitute.com

Organisation
Program for Appropriate Technology in Health (PATH)

Sponsor details
1455 NW Leary Way
Seattle
United States of America
WA 98107

Sponsor type
Research organisation

Website
http://www.path.org

Organisation
Serum Institute of India (India)

Sponsor details

Sponsor type
Not defined

Website
http://www.seruminstitute.com/

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, 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
Not provided at time of registration

Intention to publish date

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	16/06/2011		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
Results article	results	15/11/2015		Yes	No
Results article	results	15/11/2015		Yes	No
Results article	results	15/11/2015		Yes	No