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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 subjects 2 to 29 years of age

Submission date
14/08/2007

Registration date
14/08/2007

Last Edited
05/03/2019

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

Study website
http://www.meningvax.org

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
RPC217; PsA-TT-003

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 subjects 2 to 29 years of age

Study objectives
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)
1. The Gambia Government/Medical Research Council (MRC) Laboratories Joint Ethic Committee, 30/07/2007, ref: L2007.56
2. Ethics committee of the National Center for Scientific Research (Centre National de la Recherche Scientifique [CNRS]), 08/08/2007, ref: 127MSPM/DS/CNRS
3. Ethics committee of the Faculty of Medicine Pharmacy and Odonto-stomatology (Faculte de Medecine de Pharmacie et d'Odonto-Stomatologie [FMPOS]), 23/07/2007, ref: 0750/FMPOS

Study design
Phase II/III 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
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 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 rabbit complement Serum Bactericidal Assay (rSBA).

Secondary outcome measures
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

Overall study start date
20/08/2007

Completion date
20/09/2008

Eligibility

Key inclusion criteria
A subject will be eligible for inclusion if ALL of the following apply at the time of enrolment:
1. Age 2 to 29 years of age (both included)
2. Written informed consent obtained from the subject (for subjects equal to 18 years of age) /parents or legal guardian (for subjects less than 18 years of age)
3. Written informed assent from the subject if and as appropriate within the participating community (e.g., for subjects equal to 13 years of age in the Malian site, for subjects equal to 15 years of age in the Senegal site or for subjects equal to 12 years of age in the Gambia site)
4. Free of obvious health problems as established by medical history including physical examination and clinical judgement of the investigator
5. Subject/parents, or legal guardian capable and willing to come/bring their child or to receive home visits for all follow-up visits
6. Residence in the study area
7. Fully vaccinated according to the local Expanded Program on Immunisation (EPI) schedule (for subjects 2 to 3 years of age only)

Participant type(s)
Patient

Age group
Mixed

Sex
Both

Target number of participants
900

Key exclusion criteria
Subjects with any of the following criteria at study entry will not be eligible for participation:
1. Previous vaccination against Neisseria meningitidis during the six previous years
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 corticosteroids, this means prednisone, or equivalent, greater than 0.5 mg/kg/day; topical steroids including inhaled 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 judgement)

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
15. Pregnancy or lactation (a negative pregnancy test will be required before vaccination for all women of childbearing potential)
16. Previous inclusion of five family members in the study (i.e., subjects belonging to the same family - biological father, mother, child, and brothers and sisters may be included up to a maximum of five members from the same family)

Date of first enrolment
20/08/2007

Date of final enrolment
20/09/2008

Locations

Countries of recruitment
Gambia

Mali

Senegal

Switzerland

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

Sponsor information

Organisation
Serum Institute of India Limited (SIIL)

Sponsor details
212/2, Hadapsar
Pune

India
411 028

Sponsor type
Industry

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

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 (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
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