ISRCTN10763234 https://doi.org/10.1186/ISRCTN10763234

Evaluation of antibody persistence in Ghanaian children more than five years after vaccination with MenAfriVac® widely used in Sub-Saharan Africa to prevent epidemic Meningitis

Submission date
15/09/2015

Recruitment status
No longer recruiting

Registration date
29/10/2015

Overall study status
Completed

Last Edited
29/10/2020

Condition category
Nervous System Diseases

[ ] 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). In a previous study, 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) was investigated. The aim of this follow up study is to look at the group A meningitis immunity in the long-term, for children involved in the initial study.

Who can participate?
Healthy children who took part in the PsA-TT-004 study, received the PsA-TT study vaccine and who completed the final study visit in 2011 (children now aged 6 to 8 years)
OR
Healthy children who received a single dose of MenAfriVac® during the national campaign in 2012 at age 12-18 months (children now aged 4 to 6 years)

What does the study involve?
All participants have two blood samples taken 12 months apart. Immunity against group A meningitis is then 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 collection.

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?
September 2015 to December 2017

Who is funding the study?
Bill and Melinda Gates Foundation (USA)

Who is the main contact?
Dr Cheryl Keech

Contact information

Type(s)
Scientific

Contact name
Dr Niranjan Bhat

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Pers-004

Study information

Scientific Title

Evaluation of the Men A specific antibody persistence in Ghanaian children more than five years after immunization with PsA-TT (2.5 µg, 5 µg, or 10 µg polysaccharide concentration) Long-term follow-up of infants of 14-18 weeks age who participated in clinical trial PsA-TT-004 in Ghana

Study objectives
Age specific and dose specific Men A antibodies persist more than five years in children who were immunized as infants and toddlers with the PsA-TT (2.5, 5, or 10 µg polysaccharide concentration) following a two dose or single dose schedule.

This study is a follow-up study to the PsA-TT-004 study, please see: http://www.isrctn.com /ISRCTN82484612

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Navrongo Health Research Centre Institutional Review Board, 31/08/2015, ref: NHRCIRB20S
2. Ghana Health Service Ethics Review Committee, 01/09/2015, ref: GHS-ERC 02/07/15

Study design
Longitudinal observational single-center study

Primary study design
Observational

Secondary study design

Study setting(s)
Community

Study type(s)
Prevention

Participant information sheet

Health condition(s) or problem(s) studied
Meningococcal A disease

Interventions
Former PsA-TT-004 participants previously received either a two dose regimen of PsA-TT (2.5, 5, or 10 µg dosage) at 14 to 18 weeks and 9 to 12 months of age or a single dose of 10 µg PsA-TT at 9 to 12 months or at 12 to 18 months of age.
In addition, a matched age control group will be recruited among children who participated in the MenAfriVac® National Campaign in 2012 and were aged 12-18 months, inclusive when a single dose of MenAfriVac® was received during the campaign. This study comprises two time points 12 months apart to obtain blood serum for analysis and complete a case report form.

Intervention Type
Biological/Vaccine

Primary outcome measure

Meningococcal A antibody persistence will be assessed one year after recruitment and then again a year later, in terms of geometric mean titer (GMT) of meningococcal A antibody titers as measured by rSBA assay for each study group (groups 1A, 1B, 1C, 2, and 3 from the original PsA-TT-004 study and a new control group).

Secondary outcome measures
The percentage of subjects who have a 4-fold or higher response in MenA antibody titer with respect to pre-immunization MenA antibody titer (from initial study), as measure by rSBA assay will be determined one year after recruitment and then again a year later.

Overall study start date
01/01/2015

Completion date
31/12/2017

Eligibility

Key inclusion criteria
1. Enrolled in the initial study intervention group and completed the final blood draw at 36 weeks
OR
2. Received at age 12-18 months (inclusive) a single dose of MenAfriVac® during the national campaign in 2012 (new control group)

Participant type(s)
Healthy volunteer

Age group
Child

Sex
Both

Target number of participants
1028

Key exclusion criteria
1. Any chronic condition or medical/hereditary history suggesting subject would be immuno-compromised (i.e. HIV, autoimmune disease)
2. Non-residence in the study area or intent to move out within one year (new control group only)
3. 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

Date of first enrolment
18/09/2015

Date of final enrolment

04/12/2015

Locations

Countries of recruitment
Ghana

Study participating centre
Navrongo Health Research Centre
Ghana Health Service
Navrongo
Ghana
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Sponsor information

Organisation
Program for Appropriate Technology in Health

Sponsor details
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United States of America
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+1 206.285.3500
media@path.org

Sponsor type
Other

Website
www.path.org

ROR
https://ror.org/02ycvrx49

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?
Basic results		16/10/2020	23/10/2020	No	No