

Phase II, double blind, randomised, controlled study to evaluate immunogenicity, reactogenicity and safety of GlaxoSmithKline Biologicals Hib-menAC vaccine (Ghana)

| | | |
|--|--|--|
| Submission date 04/08/2004 | Recruitment status No longer recruiting | <input checked="" type="checkbox"/> Prospectively registered |
| Registration date 22/09/2004 | Overall study status Completed | <input type="checkbox"/> Protocol |
| Last Edited 19/05/2008 | Condition category Infections and Infestations | <input type="checkbox"/> Statistical analysis plan |
| | | <input checked="" type="checkbox"/> Results |
| | | <input type="checkbox"/> Individual participant data |

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr Zarifah Reed

Contact details

World Health Organization

20 Avenue Appia

Geneva-27

Switzerland

CH-1211

reedz@who.int

Additional identifiers

Protocol serial number

WHO/RPC007/759346-009

Study information

Scientific Title

Study objectives

The principal objective is to evaluate the immunogenicity, reactogenicity and safety of new heptavalent vaccine HibMenAMenC/DPTwHepB when compared to DPTwHepB/Hib in infants when administered at 6, 10 and 14 weeks of age, a schedule corresponding to that used under the EPI (Expanded Programme on Immunisation). In addition the study also aims to evaluate induction of long term immune response, and whether or not immune memory can be boosted by priming, first by measuring the persistence of response at age 12 months, and response following a small dose of plain polysaccharide vaccine at that age.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from:

1. World Health Organization (WHO) Ethics Review Committee on the 13th October 2003
2. Other review board approvals were around mid to late 2003:
 - 2.1. Program for Appropriate Technology in Health (PATH) Human Subjects Protection Committee (HSPC) (USA)
 - 2.2. National Ethics Committee of Ghana Health Service (Ghana)
 - 2.3. Navrongo Health Research Center (Ghana)
 - 2.4. London School of Hygiene and Tropical Medicine (UK)

Study design

Randomised controlled trial

Primary study design

Interventional

Study type(s)

Prevention

Health condition(s) or problem(s) studied

Vaccination against meningococcal disease

Interventions

Intramuscular administration of the vaccines at 6, 10 and 14 weeks of age:

Group 1: GlaxoSmithKline (GSK) Biologicals' Haemophilus influenzae type b (Hib)-meningitis AC (menAC) extemporaneously mixed with (GSK) Biologicals' TritanrixTM-Hepatitis B (HepB)

Group 2: (GSK) Biologicals' HiberixTM vaccine, extemporaneously mixed with (GSK) Biologicals' TritanrixTM-HepB.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

HibMenAMenC/DPTwHepB, DPTwHepB/Hib vaccines

Primary outcome(s)

1. Demonstrate immunogenicity of HibMenAMenC/DPTwHepB with respect to serum bacterial assay(SBA)-Men A and SBA-MenC
2. Demonstrate that HibMenAMenC/DPTwHepB is non-inferior to the control vaccine DPTwHepB /Hib with respect to immunogenicity of all common antigens (anti-PRP, anti-Diphtheria, anti-tetanus, anti-BP, anti-HBs)

Key secondary outcome(s)

1. Evaluate antibody persistence induced by the primary vaccination with HibMenAMenC /DPTwHepB versus DPTwHepB/Hib with respect to immunogenicity of all antigens administered at 12 months of age
2. Evaluate immune memory induced by primary vaccination with HibMenAMenC/DPTwHepB by administering 10 micrograms of each meningococcal A and C polysaccharide (1/5 of a dose of Mencevax AC) using unprimed subjects of DPTwHepB/Hib as control
3. Assess immunogenicity and safety of the primary vaccination after each vaccine dose and overall in the two study groups
4. To assess the reactogenicity and safety of the 10 micrograms of meningococcal A and C polysaccharide (1/5 of a dose of Mencevax AC) in subjects primed with either HibMenAMenC /DPTwHepB or DPTwHepB/Hib

Completion date

07/10/2005

Eligibility**Key inclusion criteria**

Healthy infants between 6 - 8 weeks of age at first vaccination.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Child

Lower age limit

6 weeks

Upper age limit

8 weeks

Sex

All

Key exclusion criteria

Any condition that may affect the health of the subject, or the interpretation of the results.

Date of first enrolment

19/01/2005

Date of final enrolment

07/10/2005

Locations

Countries of recruitment

Ghana

Switzerland

Study participating centre

World Health Organization

Geneva-27

Switzerland

CH-1211

Sponsor information

Organisation

GlaxoSmithKline (GSK) Biologicals (Ancillary study - Swiss Tropical Institute) (Belgium)

ROR

<https://ror.org/00n3pea85>

Funder(s)

Funder type

Research organisation

Funder Name

World Health Organization (WHO)/Department of Immunisation, Vaccines and Biologicals (IVB)
(Switzerland)

Results and Publications

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 | 14/05/2008 | | Yes | No |