ISRCTN35754083 https://doi.org/10.1186/ISRCTN35754083

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

Registration date
22/09/2004

Last Edited
19/05/2008

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

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet

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 measure
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)

Secondary outcome measures
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 immunogenecity 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

Overall study start date
19/01/2005

Completion date
07/10/2005

Eligibility

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

Participant type(s)
Patient

Age group
Child

Lower age limit
6 Weeks

Upper age limit
8 Weeks

Sex
Both

Target number of participants
280 healthy male and female infants

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)

Sponsor details
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Sponsor type
Industry

Website
http://www.gsk.com/worldwide/be.htm

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

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	14/05/2008		Yes	No