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Medical Condition

Compound Name

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on this study please

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ClinicalTrial.gov is a database that provides summary protocol information for ongoing clinical trials.

IFPMA.org is a search portal provided by the International Federation of Pharamceutical Manufacturers & Associations (IFPMA).

This portal provides a single entry point to search for industry sponsored clinical trials which are on existing registers and databases.

EU Clinical Trials Register is a database of all clinical trials commencing in the European Community from 1 May 2004 onwards. It has been established in accordance with Directive 2001/20/EC.

Study ID **217744/031**

Study Title

	Study to assess immunogenicity and reactogenicity of SB Biologicals' DTPa-HBV-IPV/Hib vaccine given as three-dose primary vaccination course compared to DTPa-IPV/Hib and HBV administered concomitantly at separate sites
Clinicaltrials.gov Identifier	
Sponsor	GlaxoSmithKline
Collaborators	N/A
Study Recruitment Status	Completed
Generic Name	Combined Diphteria, Tetanus, Acellular Petussis, Hepatitis B, Inactivated Polio, Haemophilus influenzae Type b Vaccine
Trade Name	
Study Indication	

- Protocol Summary

First Received	Last Updated
October 13, 2011	October 20, 2011

Title	Study to assess immunogenicity and reactogenicity of SB Biologicals' DTPa-HBV-IPV/Hib vaccine given as three-dose primary vaccination course compared to DTPa-IPV/Hib and HBV administered concomitantly at separate sites
Phase	phase 2
Acronym	
Secondary IDs	
FDA Regulated Intervention?	Yes
Section 801 Clinical Trial	Yes
Delayed Posting	No
IND/IDE Protocol	no
IND/IDE Grantor	
IND/IDE Number	
IND/IDE Serial Number	
Has Expanded Access	
Study Type	Interventional
Oversight Authority	• Slovakia: State Institute for Drug Control
Sponsor	GlaxoSmithKline
Collaborators	
Brief Summary	This study will assess the immunogenicity of GlaxoSmithKline (GSK) Biologicals' (formerly SmithKline Beecham Biologicals') DTPa-HBV-IPV/Hib (Infanrix hexa™) vaccine compared to the separate administration of

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	DTPa-HBV-IPV (Infanrix™ penta) and Hib (Hiberix™) vaccines administered at 3 and 5 months of age.	
Detailed Description		
Record Verification Date	October 12, 2011	
Status	Completed	
Why Study Stopped		
Study Start Date	September 1998	
Study Completion Date	September 1999	
Study Completion Date Type	Actual	
Primary Completion Date	September 1999	
Primary Completion Date Type	Actual	
Primary Purpose	prevention	
Allocation	Randomized	
Masking	Open Label	
Masked Subject	no	
Masked Caregiver	no	
Masked Investigator	no	
Masked Assessor	no	
Study Design (Assignment)	Parallel Assignment	
Study Classification (Endpoint)	Efficacy Study	
Primary Outcomes	• **Number of subjects with antibody titers equal to or greater than cut-off value.** Time Frame: One month after the 2nd dose of the primary vaccination course (month 3) Safety Issue: No	
Secondary Outcomes	• **Occurrence of solicited general symptoms** Time Frame: Within 4 days after each vaccination and overall Safety Issue: No • **Immunogenicity with respect to components of the study vaccines in terms of antibody titers** Time Frame: One month after the 2nd dose (Month 3), before and one month after the 3rd dose of the primary vaccination course (Months 8 and 9) Safety Issue: No	

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- **Occurrence of unsolicited symptoms**
  Time Frame: Within 30 days after each vaccination, and overall
  Safety Issue: No
- **Immunogenicity with respect to components of the study vaccines in terms of number of seropositive subjects**
  Time Frame: One month after the 2nd dose (Month 3), before and one month after the 3rd dose of the primary vaccination course (Months 8 and 9)
  Safety Issue: No
- **Occurrence of serious AEs**
  Time Frame: Throughout the entire study (approximately 9 months per subject) up to and including 30 days post-vaccination
  Safety Issue: No
- **Occurrence of solicited local symptoms**
  Time Frame: Within 4 days after each vaccination and overall
  Safety Issue: No
- **Immunogenicity with respect to components of the study vaccines in terms of number of subjects with a vaccine response**
  Time Frame: One month after the 3rd dose of the primary vaccination course (Month 9)
  Safety Issue: No

Arms

- **DTPa 1 Group**
- **DTPa 2 Group**

Interventions

- **DTPa-HBV-IPV/Hib (Infanrix-hexa™)** Type: vaccine
  Description: 3 doses administered intramuscularly into the right thigh at study month 0, 2 and 8
  Arms: DTPa 1 Group
- **HBV (Engerix™-B)** Type: vaccine
  Description: 3 doses administered intramuscularly into the left thigh at study month 0, 2 and 8
  Arms: DTPa 2 Group
- **DTPa-IPV/Hib (Infanrix-IPV/Hib™)** Type: vaccine
  Description: 3 doses administered intramuscularly into the right thigh at study month 0, 2 and 8
  Arms: DTPa 2 Group

Conditions

- Haemophilus influenzae type b (Hib)
- Pertussis
- Poliomyelitis
- Hepatitis B
- Diphtheria
- Tetanus

Keywords

- combined vaccine
- DTPa-HBV-IPV/Hib
- DTPa-IPV/Hib
- HBV
- Immunogenicity

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- Infants
- safety

Click to view inclusion/exclusion criteria

Eligibility Criteria:	**Inclusion Criteria:** • A male or female between 12 and 16 weeks of age at the time of the first vaccination. • Free of obvious health problems as established by medical history and clinical examination before entering into the study. • Written informed consent obtained from the parents or guardians of the subject after they have been advised of the risks and benefits of the study in a language which they clearly understood, and before performance of any study procedure. **Exclusion Criteria:** • Use of any investigational or non-registered drug or vaccine other than the study vaccine(s) during the study period or within 30 days preceding the first dose of study vaccine. • Administration of chronic immunosuppressants or immune-modifying drugs during the study period. • Administration of a vaccine not foreseen by the study protocol during the period starting from one month before each dose and ending one month after each dose. • Previous vaccination against diphtheria, tetanus, pertussis, hepatitis B, polio and/or Hib diseases. • History of/or intercurrent diphtheria, tetanus, pertussis, hepatitis B, polio and/or Hib disease. • Any confirmed or suspected immunosuppressive or immunodeficient condition, including human immunodeficiency virus (HIV) infection. • History of allergic disease or reaction likely to be exacerbated by any component of the vaccine, including allergic reactions to neomycin and polymyxin B. • Major congenital defects or serious chronic illness. • Progressive neurological disorders. • Administration of immunoglobulins and/or any blood products since birth and during the study period. • Acute febrile illness at the time of planned vaccination.
Gender	Both
Minimum Age	12 Weeks
Maximum Age	16 Weeks
Enrollment	312
Enrollment Type	Actual
Healthy Volunteers	yes
Central Contact	Call Center
Central Contact Phone	877-379-3718

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Central Contact Email	GSKClinicalSupportHD@gsk.com	
Overall Study Official	GSK Clinical Trials	
Overall Study Official Affiliation	GlaxoSmithKline	
Overall Study Official Role	Study Director	
Responsible Party Name/Official Title	Cheri Hudson; Clinical Disclosure Advisor	
Responsible Party Organization	GSK Clinical Disclosure	

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