



Clinical Trial Details (PDF Generation Date :- Sat, 30 Sep 2023 12:18:54 GMT)

CTRI Number	CTRI/2012/08/002872 [Registered on: 09/08/2012] - Trial Registered Prospectively		
Last Modified On	09/07/2013		
Post Graduate Thesis	No		
Type of Trial	Interventional		
Type of Study	Vaccine		
Study Design	Randomized, Parallel Group, Multiple Arm Trial		
Public Title of Study	Safety, Immunogenicity & lot consistency study of DPT-HepB-Hib pentavalent vaccine (Shan 5) as compared to a comparator pentavalent vaccine.		
Scientific Title of Study	Safety, Immune Lot-to-Lot Consistency and Non-Inferiority of Shan 5 (DTwP-HepB-Hib) Vaccine in Comparison to Pentavac SD When Administered as a Single Booster Dose at 15-18 months and Three Doses at 6-8, 10-12 and 14-16 Weeks of Age in Healthy Indian Children and Infants.		
Secondary IDs if Any	Secondary ID	Identifier	
	SH501 Version 1.0 dated 14 APRIL 2012	Protocol Number	
Details of Principal Investigator or overall Trial Coordinator (multi-center study)	Details of Principal Investigator		
	Name	Dr Mandeep Singh Dhingra MD	
	Designation	Chief Clinical Officer, Chief PV and CQA Officer	
	Affiliation	Shantha Biotechnics Limited	
	Address	Shantha Biotechnics Limited, 3rd and 4th Floor, Vasantha Chambers, 5-10-173, Fateh Maidan Road, Basheer Bagh, Hyderabad. Hyderabad ANDHRA PRADESH 500004 India	
	Phone	040-66301000	
	Fax		
	Email	drmandeep@shanthabiotech.co.in	
	Details Contact Person (Scientific Query)	Details Contact Person (Scientific Query)	
		Name	Dr Mandeep Singh Dhingra MD
Designation		Chief Clinical Officer, Chief PV and CQA Officer	
Affiliation		Shantha Biotechnics Limited	
Address		Shantha Biotechnics Limited, 3rd and 4th Floor, Vasantha Chambers, 5-10-173, Fateh Maidan Road, Basheer Bagh, Hyderabad. ANDHRA PRADESH 500004 India	
Phone		040-66301000	
Fax			
Email		drmandeep@shanthabiotech.co.in	
Details Contact Person (Public Query)	Details Contact Person (Public Query)		
	Name	Dr Mandeep Singh Dhingra MD	
	Designation	Chief Clinical Officer, Chief PV and CQA Officer	
	Affiliation	Shantha Biotechnics Limited	
	Address	Shantha Biotechnics Limited, 3rd and 4th Floor, Vasantha Chambers, 5-10-173, Fateh Maidan Road, Basheer Bagh, Hyderabad.	



	ANDHRA PRADESH 500004 India			
Phone	040-66301000			
Fax				
Email	drmandeep@shanthabiotech.co.in			
Source of Monetary or Material Support	Source of Monetary or Material Support			
	> Shantha Biotechnics Limited			
Primary Sponsor	Primary Sponsor Details			
Name	Shantha Biotechnics Limited			
Address	Shantha Biotechnics Limited, 3rd and 4th Floor, Vasantha Chambers, 5-10-173, Fateh Maidan Road, Basheer Bagh, Hyderabad. 500004. AP, India			
Type of Sponsor	Pharmaceutical industry-Indian			
Details of Secondary Sponsor	Name	Address		
	NIL	NIL		
Countries of Recruitment	List of Countries			
	India			
Sites of Study	Name of Principal Investigator	Name of Site	Site Address	Phone/Fax/Email
	Dr Sanjay Lalwani	Bharati Vidyapeeth deemed university medical college	Department of Pediatrics Bharati Hospital & Research Centre Katraj-Dhankawadi Road, Pune-411043, Maharashtra, India Pune MAHARASHTRA	020-40555555 sanjaylalwani2007@rediffmail.com
	Dr Jugesh Chhatwal	Christian medical College & Hospital-Ludhiana	Department of Pediatrics, Christian medical College & Hospital Brown Road Ludhiana-141008 Punjab, India Ludhiana PUNJAB	0161-5026999 jugeshchhatwal@rediffmail.com
	Dr Leni Grace Mathew	Christian Medical College (CMC) Hospital Vellore	Department of pediatrics, Christian medical College & Hospital, P.B. No.3, Ida Scudder Road, Vellore-632004, Tamil Nadu, India Vellore TAMIL NADU	0416-2283350 lenimathew@cmcvellore.ac.in
	Dr Ritabrata Kundu	Institute of Child Health	Department of pediatrics Institute of Child Health 11, Dr. Bireswari Guha Street, Kolkata - 700 017, West Bengal, India South Twentyfour Parganas WEST BENGAL	033-22905686 rkundu22@gmail.com



Dr M D Ravi	J.S.S Medical College	Department of pediatrics J.S.S Medical College Ramanuja Road Agrahara Mysore-570004,Karnataka,India Mysore KARNATAKA	0821-2548340 ravimdped@gmail.com
Dr S M Dhaded	Jawaharlal Nehru Medical College KLES Dr. Prabhakar Kore Hospital and MRC	Department of pediatrics KLES Dr. Prabhakar Kore Hospital and MRC Nehru Nagar Belgaum-590010 karnataka, India Belgaum KARNATAKA	0831-2471350 drdhadedsm@gmail.com
Dr A P Dubey	Maulana Azad Medical College	Department of Pediatrics, Maulana Azad Medical College, Bahadur Shah Zafar Marg, Delhi Gate New Delhi-110002 New Delhi DELHI	011-23236031 apdubey52@rediffmail.com
Dr Dulari J Gandhi	S.B.K.S Medical Institute & Research Center	Department of Pediatrics, S.B.K.S Medical Institute & Research Center At/Po. Piparia, Waghodia Road, Ta: Waghodia, Vadodara -390001,Gujarat Vadodara GUJARAT	02668-245262 djg_48@yahoo.co.in
Dr Madhu Gupta	School of Public Health, Post Graduate Institute of Medical Education & Research (PGIMER)	Department of Community Medicine, School of Public Health, PGIMER, Chandigarh-160 012 Chandigarh CHANDIGARH	0172-2744993 madhugupta21@gmail.com
SDSharma	SMS Medical College & Attached Hospitals	Department of Pediatrics SMS Medical College & Attached Hospitals Sir Padampat M.C.H. Institute (J.K. Lone Hospital) J.L.N. Marg, Jaipur-302004, Rajasthan, India Jaipur RAJASTHAN	0141-2619827 sdsharmajp@yahoo.co.in
Dr Sandeep Bavdekar	T N Medical College	Department of pediatrics T N Medical College and BYL Nair Hospital Dr A L Nair Road, Mumbai Central, Mumbai,400008,Maharashtra,India Mumbai (Suburban)	022-23027138 sandeep.bavdekar@gmail.com



		MAHARASHTRA	
Details of Ethics Committee	Name of Committee	Approval Status	Date of Approval
	Bharati Vidyapeeth deemed university medical college, Pune, IEC	Approved	07/08/2012
	Christian medical College & Hospital, Vellore, IEC	Approved	11/09/2012
	Christian Medical College (CMC) Hospital, Ludhiana IEC	Approved	26/05/2012
	Institute of Child Health, Kolkata IEC	Approved	29/06/2012
	J.S.S Medical College, Mysore IEC	Approved	18/05/2012
	Jawaharlal Nehru Medical College, Belgaum, KLE, IEC	Approved	18/06/2012
	Maulana Azad Medical College, New Delhi IEC	Approved	11/06/2012
	S.B.K.S Medical Institute & Research Center, Vadodra, IEC	Approved	04/06/2012
	School of Public Health, Post Graduate Institute of Medical Education & Research (PGIMER), Chandigarh IEC	Approved	30/04/2012
	SMS Medical College & Attached Hospitals, Jaipur, IEC	Approved	25/08/2012
	T N Medical College, Mumbai, IEC	Approved	06/08/2012
Regulatory Clearance Status from DCGI	Status		Date
	Approved/Obtained		31/07/2012
Health Condition / Problems Studied	Health Type		Condition
	Healthy Human Volunteers		Prevention against Diphtheria, Tetanus, Pertussis, Hepatitis-B and Haemophilus Influenzae type B diseases.
Intervention / Comparator Agent	Type	Name	Details
	Intervention	Shan 5™	DTwP-HepB-Hib pentavalent combination vaccine Dose:0.5 ml Frequency:3 dose series with 1 month gap between each dose (i.e at 6-8 week, 10-12 week and 14-16 week) and Single dose at 15-18 month Duration: Not Applicable Route:Intramuscular
	Comparator Agent	Pentavac SD™	DTwP-HepB- Hib combined vaccine Dose:0.5 ml Frequency:3 dose series with 1 month gap between each dose (i.e at 6-8



		week, 10-12 week and 14-16 week) and Single dose at 15-18 month Duration: Not Applicable Route:Intramuscular
Inclusion Criteria	Inclusion Criteria	
	Age From	42.00 Day(s)
Age To	18.00 Month(s)	
Gender	Both	
Details	<p>1.Children between the age of 15-18 months whose parents/LAR is willing to give written informed consent prior to the study inclusion.
 2.Children with good general health as determined by: Medical history, Physical examination and Clinical judgment of the investigator.
 3.Children who have completed primary immunization series of diphtheria, tetanus, pertussis by virtue of previous immunization and have not received the booster dose scheduled at 15-18 months of age.
 4.Children who require a dose of Hepatitis B as per National Immunization schedule/IAP recommendation because of one of the following reasons:
 i)Has not received any dose of Hepatitis B or
 ii)Have not completed primary vaccination against Hepatitis B
 5.Children who require a dose of Haemophilus influenzae type b as per National Immunization schedule/IAP recommendation because of one of the following reasons:
 i)Has not received any dose of Hib or
 ii)Completed primary vaccination against Hib but not received the booster dose.
 6.Judged to be able to attend all scheduled study visits and to comply with study procedures.
 1. Infants between 6-8 weeks of age on the day of inclusion
 2. Born at full term of pregnancy (?37 weeks) with a birth weight ?2.5 kg.
 3. Informed consent form signed by one or both parents or by the legally acceptable representative as per local requirements
 4. Able to attend all scheduled visits and to comply with all trial procedures
</p>	
Exclusion Criteria	Exclusion Criteria	
	Details	<p>1.Participation in another clinical trial in the 4 weeks preceding the first trial vaccination 2.Planned participation in another clinical trial during the present trial period 3.Known or suspected congenital or acquired immunodeficiency, immunosuppressive therapy, or long-term systemic corticosteroids therapy(prednisone or equivalent at ? 0.5 mg/kg/day) for more than 2 consecutive weeks within the past 2 months) 4.Known systemic hypersensitivity to any of the vaccine components or history of a life-threatening reaction to the trial vaccine or a vaccine containing the same substances.(The list of vaccines components is included in the investigator's brochure) 5.Chronic illness at a stage that could interfere with trial conduct or completion, in the opinion of the Investigator (Chronic illness may include, but is not limited to, haematological, hepatic, renal, cardiac or respiratory disease or autoimmune disorders, diabetes, atopic conditions, congenital defects, convulsions, or encephalopathy etc.) 6.Blood or blood-derived products received in the past (since birth) or current or planned administration during the trial (including immunoglobulins) that might interfere with the assessment of the immune response 7.Any vaccination before trial vaccination except OPV, HepB and BCG given at birth. (Cohort 2 only) 8.Any planned vaccination until one month after the last trial vaccination except; (i)OPV during National Immunization Days (For both the Cohorts),</p>



	(ii)BCG if not given at birth (Cohort 2 only). 9.Documented history of pertussis, tetanus, diphtheria, poliomyelitis, Haemophilus influenzae type b or Hepatitis B infection(s) (confirmed either clinically, serologically or microbiologically) 10.Previous vaccination against pertussis, tetanus, diphtheria or Haemophilus influenzae type b infections (Cohort 2 only) 11.Known personal or maternal history of HIV, Hepatitis B (HBsAg) or Hepatitis C seropositivity. 12.Known coagulopathy, thrombocytopenia or a bleeding disorder preceding inclusion contraindicating IM vaccination 13.History of seizures 14.Febrile illness (temperature $\geq 38.0^{\circ}\text{C}$) or moderate or severe acute illness/infection on the day of inclusion, according to the Investigator judgment				
Method of Generating Random Sequence	Permuted block randomization, fixed				
Method of Concealment	Sequentially numbered, sealed, opaque envelopes				
Blinding/Masking	Participant Blinded				
Primary Outcome	<table border="1"> <thead> <tr> <th>Outcome</th> <th>Timepoints</th> </tr> </thead> <tbody> <tr> <td>Seroprotection/ Seroresponse rates to five antigens for immunogenicity</td> <td>one month after vaccination</td> </tr> </tbody> </table>	Outcome	Timepoints	Seroprotection/ Seroresponse rates to five antigens for immunogenicity	one month after vaccination
Outcome	Timepoints				
Seroprotection/ Seroresponse rates to five antigens for immunogenicity	one month after vaccination				
Secondary Outcome	<table border="1"> <thead> <tr> <th>Outcome</th> <th>Timepoints</th> </tr> </thead> <tbody> <tr> <td>Safety of the vaccines</td> <td>One month and six months after vaccination</td> </tr> </tbody> </table>	Outcome	Timepoints	Safety of the vaccines	One month and six months after vaccination
Outcome	Timepoints				
Safety of the vaccines	One month and six months after vaccination				
Target Sample Size	Total Sample Size=1100 Sample Size from India=1100 Final Enrollment numbers achieved (Total)=Applicable only for Completed/Terminated trials Final Enrollment numbers achieved (India)=Applicable only for Completed/Terminated trials				
Phase of Trial	Phase 3				
Date of First Enrollment (India)	03/09/2012				
Date of First Enrollment (Global)	No Date Specified				
Estimated Duration of Trial	Years=1 Months=7 Days=0				
Recruitment Status of Trial (Global)	Not Applicable				
Recruitment Status of Trial (India)	Closed to Recruitment of Participants				
Publication Details					
Brief Summary	<p>This clinical study will assess the immunogenicity and safety of Shantha's DTPwHB-HIB (Shan 5TM) combined vaccine <i>against</i> comparators vaccine given simultaneously to different groups as a single booster dose at 15-18 months and three-dose primary vaccination at 6-8,10-12, and 14-16 weeks of age subjects.</p> <p>Study will evaluate equivalence of immunogenicity of three lots of Shan 5 and its non-inferiority to comparator vaccine in terms of seroprotection/ seroresponse rates to all antigens one month after a three-dose primary series (6-8, 10-12 and 14-16 weeks).</p>				