Clinical Trial Details (PDF Generation Date :- Sat, 03 Jun 2023 09:24:31 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. Biresh 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, PGIMR, 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	Is Independent Ethics Committee?
Bharati Vidyapeeth deemed university medical college, Pune, IEC	Approved	07/08/2012	No
Christian medical College & Hospital, Vellore, IEC	Approved	11/09/2012	No
Christian Medical College (CMC) Hospital, Ludhiana IEC	Approved	26/05/2012	No
Institute of Child Health, Kolkata IEC	Approved	29/06/2012	No
J.S.S Medical College, Mysore IEC	Approved	18/05/2012	No
Jawaharlal Nehru Medical College, Belgaum, KLE, IEC	Approved	18/06/2012	No
Maulana Azad Medical College, New Delhi IEC	Approved	11/06/2012	No
S.B.K.S Medical Institute & Research Center, Vadodra, IEC	Approved	04/06/2012	No
School of Public Health, Post Graduate Institute of Medical Education & Research (PGIMER), Chandigarh IEC	Approved	30/04/2012	No
SMS Medical College & Attached Hospitals, Jaipur, IEC	Approved	25/08/2012	No
T N Medical College, Mumbai, IEC	Approved	06/08/2012	No

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 Frquency: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 Frquency: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	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

Exclusion Criteria

Exclusion Criteria	
Details	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),

	(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 ?38.0°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

Outcome	Timepoints
Seroprotection/ Seroresponse rates to five antigens for immunogenicity	one month after vaccination

Secondary Outcome

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	This clinical study will assess the immunogenicity and safety of Shantha's DTPwHB-HIB (Shan 5 [TM]) combined vaccine *against* 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. 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).