Clinical Trial Details (PDF Generation Date :- Sun, 27 Nov 2022 10:24:43 GMT)

CTRI Number	CTRI/2013/09/003961 [Registered on: 06/09/2013] - **Trial Registered Prospectively**
Last Modified On	12/03/2019
Post Graduate Thesis	No
Type of Trial	Interventional
Type of Study	Vaccine Biological Preventive
Study Design	Randomized, Parallel Group, Active Controlled Trial
Public Title of Study	A clinical trial to study the safety profile of Serum Institute of India's 10-valent Pneumococcal Conjugate Vaccine (SIILPCV10) in healthy Indian young adults.
Scientific Title of Study	"A Phase 1, Prospective, Randomized, Two-Arm, Active Controlled, Double-Blind Study to Evaluate the Safety and Tolerability of Serum Institute of India's 10-valent Pneumococcal Conjugate Vaccine (SIILPCV10) in Healthy Indian Young Adults"

Secondary IDs if Any

Secondary ID	Identifier
PCV-10-001, Version 3.1, dated 14-Feb-14	Protocol Number

Details of Principal Investigator or overall Trial Coordinator (multi-center study)

Details of Principal Investigator	
Name	Dr Nithya Gogtay
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Details Contact Person (Scientific Query)

Details Contact Person (Scientific Query)	
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Details Contact Person (Public Query)

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Email	vistasp.sethna@seruminstitute.com

Source of Monetary or Material Support

Source of Monetary or Material Support

Primary Sponsor

Primary Sponsor Details	
Name	Serum Institute of India Limited
Address	212/2, Off Soli Poonawalla Road, Hadapsar, Pune – 411028, 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 Nithya Gogtay	Seth G S Medical College & KEM Hospital, Mumbai	Department of Clinical Pharmacology, 1st Floor, MS Building Acharya Donde Marg, Parel, Mumbai-400012 Mumbai MAHARASHTRA	02224133767 02224112871 njgogtay@hotmail.com

Details of Ethics Committee

Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
Institutional Ethics Committee-I	Approved	23/07/2013	No

Regulatory Clearance Status from DCGI

Status	Date
Approved/Obtained	04/09/2013

Health Condition / Problems Studied

Health Type	Condition
Healthy Human Volunteers	Active immunization for the prevention of disease caused by S.Pneumoniae, including sepsis, meningitis, bacteremia, pneumonia and acute otitis media.

Intervention / Comparator Agent

Type	Name	Details
Intervention	10-valent Pneumococcal Conjugate Vaccine (SIILPCV10; SIIL)	0.5 mL IM, non-dominant upper arm, single administration
Comparator Agent	23-valent Pneumococcal Polysaccharide Vaccine (Pneumovax® 23; Merck)	0.5 mL IM, non-dominant upper arm, single administration

Inclusion Criteria

Inclusion Criteria	
Age From	18.00 Year(s)
Age To	40.00 Year(s)
Gender	Both
Details	Healthy young Indian adults between 18 to 40 (inclusive) years of age. Note: “Healthy” being those without acute or chronic, clinically significant pulmonary, cardiovascular, hepatobiliary, gastrointestinal, renal, neurological, mental or hematological

	functional abnormality or illness that requires medical therapy, as determined by medical history or clinical assessment before entering the study. Subjects who provide voluntary written informed consent to participate in the study and are capable of comprehending and complying with study requirements and procedures, able and willing to complete subject diary and to return for all scheduled follow-up visits, and have expressed availability for the required study period, with access to a consistent means of telephone contact, either residential land line or mobile. Adult male subjects willing to follow acceptable methods of contraception (e.g. condom, with or without spermicide) or practice abstinence and agreeing not to make their female partners pregnant from the time of vaccination until the end of the study. Adult female subjects who are not surgically sterile must have a negative serum pregnancy test on enrolment and prior to vaccination, and will be advised through the informed consent process to avoid becoming pregnant over the duration of the study, and must agree to employ an effective form of birth control for the duration of the study. Note: Acceptable forms of birth control are: credible history of continuous abstinence from heterosexual activity, hormonal contraceptive (oral, injectable, implant, patch, or ring), double-barrier contraceptives (condom or diaphragm, either with spermicide) and IUD. When using contraceptives, subjects must have been using their current contraceptive for the past 3 months to be eligible. Women with documented sterilization via tubal ligation or hysterectomy or having surgically sterilized male partners may be enrolled and are not subject to pregnancy testing. Subjects willing to avoid consumption (ingestion) of chronic herbal medication during the course of the study.

Exclusion Criteria

Exclusion Criteria	
Details	Use of any investigational or non-registered drug within 90 days prior to the administration of study vaccine or planned during the course of study participation. History of previous vaccination against Streptococcus pneumoniae or recent history of Streptococcus pneumoniae infection in the past 2 years. History of administration of any non-study vaccine within 30 days prior to administration of study vaccine or planned vaccination during the course of study participation. History of allergic disease or history of a serious reaction to any prior vaccination or known hypersensitivity to any component of the study vaccines. History of anaphylactic shock. Acute illness (moderate or severe) and/or fever (oral temperature 38°C). Receipt of antibiotics (oral or injected) from 5 days before screening through to randomization. Immunosuppression or immunodeficiency (inclusive of HIV, Hep B, Hep C) as shown by serological examination at screening. Disorders that require chronic administration (defined as more than 14 consecutive days) of immunosuppressants or other immune-modifying drugs within the past 6 months prior to the

	administration of the study vaccine. An immunosuppressant dose of glucocorticoid will be defined as a systemic dose 10 mg of prednisone per day. The use of topical glucocorticoids will be permitted. Administration of immunoglobulins and/or any blood products within the 6 months preceding enrolment in the study; or anticipation of such administration during the study period. Known disturbance of coagulation or other blood disorder (e.g. thalassemia, thrombocytopenia, disorders of the lymphocytes, anemias, etc) or receipt of anti-coagulants in the past 3 weeks (prn aspirin and NSAIDs are acceptable). History of meningitis or seizures or any neurological disorder or major psychiatric disorder. Acute or chronic, clinically significant pulmonary, cardiovascular, hepatobiliary, gastrointestinal, renal, neurological, or hematological functional abnormality or major congenital defects or illness that requires medical therapy, as determined by medical history or clinical assessment. Any medical or social condition that in the opinion of the investigator will interfere with the study objectives or pose a risk to the study subject or may prevent the subject from completing the study follow up. Suspicion or recent history (within the past year) of alcohol or substance abuse. Female subjects who are pregnant or breast-feeding. An employee (or first degree relative of employee) of the Sponsor, the CRO, or any investigator or site personnel. Any screening laboratory test result outside normal parameters and deemed by the clinician to be clinically significant.

Method of Generating Random Sequence	Stratified block randomization
Method of Concealment	Centralized
Blinding/Masking	Participant, Investigator, Outcome Assessor and Date-entry Operator Blinded

Primary Outcome

Outcome	Timepoints
Safety and Tolerability following IM injection of SIILPCV10 vaccine for occurrence, severity, and relationship to vaccination of solicited, unsolicited Adverse Events and SAEs.	Solicited adverse events (local and systemic) during the 7 day follow-up period post vaccination. Unsolicited adverse events during the 28-Day follow-up period post vaccination SAEs during the entire study period.

Secondary Outcome

Outcome	Timepoints
Safety and Tolerability following IM injection of SIILPCV10 vaccine versus Active Comparator for occurrence, severity, and relationship to vaccination of solicited, unsolicited Adverse Events, SAEs and Safety Laboratory parameters (Hematological, Serum Chemistry, Organ	Solicited adverse events (local and systemic) during the 7 day follow-up period post vaccination. Unsolicited adverse events during the 28-Day follow-up period post vaccination.

	Function) which are of clinical significance and related to vaccination.	SAEs during the entire study period. Safety Laboratory parameters at day 7.
Target Sample Size	**Total Sample Size=**34 **Sample Size from India=**34 **Final Enrollment numbers achieved (Total)=**34 **Final Enrollment numbers achieved (India)=**34
Phase of Trial	Phase 1
Date of First Enrollment (India)	18/06/2014
Date of First Enrollment (Global)	No Date Specified
Estimated Duration of Trial	**Years=**0 **Months=**4 **Days=**0
Recruitment Status of Trial (Global)	Not Applicable
Recruitment Status of Trial (India)	Completed
Publication Details	
Brief Summary	This is a Phase 1 Safety study in healthy young Indian adults. The study is based on the hypothesis that intramuscular administration of SIILPCV10 in healthy Indian subjects will be safe and well tolerated. On successful completion, this early safety study will lead to later phase and pivotal non-inferiority safety and immunogenicity trials in the target population, i.e. toddlers and infants, aimed at Indian licensure of SIILPCV10.