

# A phase I, double-blind, randomized study to evaluate the safety and immunogenicity of a new Meningococcal A Conjugate vaccine versus a Meningococcal Polysaccharide A+C reference vaccine and a Tetanus Toxoid control vaccine, given as single intramuscular injections in healthy adults from 18 to 35 years of age (India)

<b>Submission date</b> 22/07/2005	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 22/07/2005	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 01/03/2019	<b>Condition category</b> Infections and Infestations	<input type="checkbox"/> 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

**Protocol serial number**

PsA-TT-001

## Study information

**Scientific Title**

A phase I, double-blind, randomized study to evaluate the safety and immunogenicity of a new Meningococcal A Conjugate vaccine versus a Meningococcal Polysaccharide A+C reference vaccine and a Tetanus Toxoid control vaccine, given as single intramuscular injections in healthy adults from 18 to 35 years of age (India)

**Study objectives**

Exploratory study whose primary objective is to test reactogenicity and safety. The comparison between groups will be descriptive.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Ethics approval received 23/06/2005

**Study design**

Phase I double-blind randomised trial

**Primary study design**

Interventional

**Study type(s)**

Prevention

**Health condition(s) or problem(s) studied**

Meningococcal disease

**Interventions**

Single intramuscular injection of one of the following:

1. Study vaccine group: Serum Institute of India Limited (SIIL) PsA-TT (Meningococcal A Polysaccharide conjugated to Tetanus Toxoid)
2. Reference vaccine group: Sanofi Pasteur Meningococcal Polysaccharide Vaccine A+C
3. Control vaccine group: Serum Institute of India Limited (SIIL) Tetanus Toxoid (Adsorbed) IP

**Intervention Type**

Biological/Vaccine

**Phase**

Phase I

**Primary outcome(s)**

Incidence of adverse events including solicited adverse events and laboratory abnormalities over 4 weeks post-vaccination

**Key secondary outcome(s)**

1. Descriptive assessment of the immune response 4 weeks post-vaccination in terms of serum bactericidal activity using baby rabbit complement (SBA/BRC) and anti-PsA IgG response
2. Descriptive assessment of the persistence of an immune response 24 and 48 weeks post-vaccination in terms of SBA/BRC and anti-PsA IgG response

**Completion date**

31/07/2006

**Eligibility****Key inclusion criteria**

Healthy adults between 18 and 35 years of age

**Participant type(s)**

Healthy volunteer

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**Key exclusion criteria**

Any condition that may affect the health of the subject or the interpretation of the results; pregnancy or lactation

**Date of first enrolment**

01/08/2005

**Date of final enrolment**

31/07/2006

**Locations****Countries of recruitment**

India

Switzerland

**Study participating centre**

## World Health Organization

Geneva  
Switzerland  
CH-1211

## Sponsor information

### Organisation

Serum Institute of India Limited (SIIL) (Secondary Sponsor - Program for Appropriate Technology in Health [PATH], USA)

### ROR

<https://ror.org/04jk2xb11>

## Funder(s)

### Funder type

Charity

### Funder Name

Program for Appropriate Technology in Health (PATH) (USA) - grant from the Bill and Melinda Gates Foundation

## Results and Publications

### 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?
<a href="#">Results article</a>	results	15/11/2015		Yes	No
<a href="#">Results article</a>	results	15/11/2015		Yes	No