

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)

Submission date 22/07/2005	Recruitment status No longer recruiting	☒ Prospectively registered ☐ Protocol
Registration date 22/07/2005	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 01/03/2019	Condition category Infections and Infestations	☐ 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

Primary study design

Interventional

Study design

Phase I double-blind randomised trial

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?
Results article	results	15/11/2015		Yes	No
Results article	results	15/11/2015		Yes	No