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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

Registration date
22/07/2005

Last Edited
01/03/2019

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Infections and Infestations

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

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

Secondary outcome measures
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

Overall study start date
01/08/2005

Completion date
31/07/2006

Eligibility

Key inclusion criteria
Healthy adults between 18 and 35 years of age

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
72

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)

Sponsor details
212/2, Hadapsar
Pune
India
411028
+91 (0)206 993 900 ext. 2384
contact@seruminstitute.com

Sponsor type
Industry

Website
http://www.seruminstitute.com/

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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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