

Brazilian Meningococcal B Vaccine: Safety and Immunogenicity Study

Submission date 17/02/2006	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 16/03/2006	Overall study status Completed	☐ Protocol
Last Edited 17/03/2006	Condition category Infections and Infestations	☐ Statistical analysis plan
		☐ Results
		☐ Individual participant data
		☐ Record updated in last year

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
0047.0.009.000-05

Study information

Scientific Title

Study objectives
Vaccine adverse events occur in acceptable levels for human use

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved by the Committee of Evandro Chagas Clinical Research Institute on 28/02/2005, reference number: CAAE-0047.0.009.000-05

Primary study design

Interventional

Study design

Open, phase 1 trial

Study type(s)

Prevention

Health condition(s) or problem(s) studied

Meningococcal disease serogroup B

Interventions

1. Three doses of three different concentrations of Brazilian meningococcal B vaccine
2. Blood, urine, faeces specimens
3. Electrocardiogram (ECG), x-ray

Intervention Type

Drug

Phase

Phase I

Drug/device/biological/vaccine name(s)

Vaccine for meningococcal B disease

Primary outcome(s)

Safety 30 days after immunization

Key secondary outcome(s)

Immunogenicity 30 days after immunization

Completion date

30/12/2006

Eligibility**Key inclusion criteria**

1. 18-44 years of age
2. Willingness to comply with protocol requirements
3. Healthy volunteers

4. Ability to understand informed consent form
5. Human Immunodeficiency Virus (HIV) negative
5. Non-pregnant

Participant type(s)

Healthy volunteer

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Upper age limit

44 Years

Sex

All

Key exclusion criteria

1. Nursing women
2. Use of different substances in the previous 14-60 days such as immunosuppressive therapy and other vaccines
3. Prior history of serious adverse event to vaccines
4. Prior history of chronic diseases such as hypertension and diabetes
5. Autoimmune diseases
6. Alcohol and drug abuse

Date of first enrolment

02/01/2006

Date of final enrolment

30/12/2006

Locations**Countries of recruitment**

Brazil

Study participating centre

Av. Brasil 4365

Rio de Janeiro

Brazil

21040-900

Sponsor information

Organisation

Bio-Manguinhos/Fiocruz (Brazil)

ROR

<https://ror.org/05gj5j117>

Funder(s)

Funder type

Industry

Funder Name

Bio-Manguinhos/Fiocruz

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration