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Brazilian Meningococcal B Vaccine: Safety and Immunogenicity Study

Submission date	Recruitment status	[_] Prospectively registered
17/02/2006	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
16/03/2006	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
17/03/2006	Infections and Infestations	[_] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Study design
Open, phase 1 trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Prevention

Participant information sheet

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 measure
Safety 30 days after immunization

Secondary outcome measures
Immunogenicity 30 days after immunization

Overall study start date
02/01/2006

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

Age group
Adult

Lower age limit
18 Years

Upper age limit
44 Years

Sex
Both

Target number of participants
30

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)

Sponsor details
Av. Brasil 4365
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Sponsor type
Industry

Website
http://www.bio.fiocruz.br

ROR
https://ror.org/05gj5j117

Funder(s)

Funder type
Industry

Funder Name
Bio-Manguinhos/Fiocruz

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