ISRCTN70123783 https://doi.org/10.1186/ISRCTN70123783

# Brazilian conjugated meningococcal C vaccine: safety and immunogenicity

| Submission date | Recruitment status | [_] Prospectively registered |
|---|---|---|
| 16/02/2006 | 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

**Contact name**
Dr Andre Perisse

**Contact details**
Av. Brasil 4365
Rio de Janeiro
Brazil
21040-900
+55 21 3882 9479
areynaldo@bio.fiocruz.br

## Additional identifiers

**Protocol serial number**
0060.0.009.000-05

## 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 8/08/2005, reference number: CAAE-0060.0.009.000-05

### Study design
Open, phase 1 trial

### Primary study design
Interventional

### Study type(s)
Prevention

### Health condition(s) or problem(s) studied
Meningococcal disease serogroup C

### Interventions
1. Brazilian conjugate meningococcal C vaccine
2. Blood, urine, faeces specimens
3. Electrocardiogram (ECG), x-ray

### Intervention Type
Drug

### Phase
Phase I

### Drug/device/biological/vaccine name(s)
Brazilian conjugated meningococcal C vaccine

### Primary outcome(s)
Safety assessment 30 days after immunization

### Key secondary outcome(s))
Immunogenicity 30 days after immunization

### Completion date
30/04/2006

## Eligibility

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

4. Ability to understand consent form
5. Human Immunodeficiency Virus (HIV) negative
6. 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 immunosupressive 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. Alcohol and drug abuse

### Date of first enrolment
02/01/2006

### Date of final enrolment
30/04/2006

## 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