# Safety and immunogenicity of meningococcus C conjugate vaccine

Submission date	Recruitment status	[X] Prospectively registered
02/12/2008	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
10/12/2008	Completed	Results
Last Edited	Condition category	Individual participant data
10/12/2008	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 Reinaldo Martins

#### Contact details

Av. Brasil 4365 Manguinhos Rio de Janeiro Brazil 21040-900

# Additional identifiers

## Protocol serial number

ASCLIN/01/2008

# Study information

#### Scientific Title

Safety and immunogenicity of conjugate vaccine for meningococcal C disease: a randomised study

#### **Study objectives**

Bio-Manguinhos conjugate vaccine against meningococcus C is safe and immunogenic in young healthy adults.

#### Ethics approval required

Old ethics approval format

#### Ethics approval(s)

Ethics Committee of Evandro Chagas Institute for Clinical Research (Comitê de Ética do Instituto de Pesquisa Clínica Evandro Chagas) gave approval on the 15th February 2008 (ref: CAAE 0068.0.009.000-07)

#### Study design

Randomised controlled blinded study

#### Primary study design

Interventional

#### Study type(s)

Treatment

#### Health condition(s) or problem(s) studied

Meningococcus C disease

#### **Interventions**

- 1. 30 volunteers will receive meningococcus C vaccine conjugate to tetanus toxoid from Bio-Manguinhos, single 0.5 ml dose  $(10 \mu g) \text{ IM}$  (intramuscularly)
- 2. 30 volunteers will receive a similar commercial vaccine (reference vaccine), same dose and schedule

#### Intervention Type

Drug

#### Phase

**Not Specified** 

## Drug/device/biological/vaccine name(s)

Meningococcus C conjugate vaccine

#### Primary outcome(s)

Frequency/intensity of adverse events during 30 days after vaccination.

## Key secondary outcome(s))

- 1. Serological conversion, defined as prevaccinal sera non-reactive to meningococcus C, and post-immunisation sera reactive (titre greater than or equal to 8, reciprocal of dilution)
- 2. Titre of antibodies to meningococcus C after immunisation (intensity of immune response)
- 3. Measurement of antibodies just before and 30 days after vaccination

## Completion date

01/12/2009

# **Eligibility**

#### Key inclusion criteria

- 1. Healthy
- 2. Both sexes
- 3. Aged between 18 and 50 years
- 4. Capable of understanding and signing Free and Informed Consent Form
- 5. Intellectual level which permits filling out records of adverse events at home
- 6. Capable of understanding risks of the experiment
- 7. Willing test for human immunodeficiency virus (HIV), hepatitis B virus (HBV) and hepatitis C virus (HCV)
- 8. Clinical examination without significant abnormalities
- 9. Laboratorial tests within normal range, or only with clinically non-significant alterations
- 10. Pre-vaccinal level of antibodies against tetanus below 5 IU/mL
- 11. Negative pregnancy test

#### Participant type(s)

**Patient** 

#### Healthy volunteers allowed

No

#### Age group

Adult

### Lower age limit

18 years

#### Upper age limit

50 years

#### Sex

All

#### Key exclusion criteria

- 1. Pregnancy or breastfeeding
- 2. Personal history of meningitis, any kind
- 3. Previous serious adverse event to any vaccination
- 4. Severe adverse event to tetanus toxoids
- 5. Vaccination against tetanus in the last 2 years
- 6. Anti-allergic vaccines 14 days or less before vaccination
- 7. Blood products in the last 12 months
- 8. Any vaccination 30 days or less before vaccination in test
- 9. Chronic use of any medication, except trivial ones
- 10. Previous use of cytotoxic or immunosuppressive therapy
- 11. Asthma which requires hospital care
- 12. Serious angioedema or anaphylaxis

#### Date of first enrolment

01/01/2009

## Date of final enrolment

01/12/2009

# 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

Government

#### **Funder Name**

Brazilian Ministry of Science and Technology (MCT) (Brazil) - Financing Agency for Studies and Projects (Financiadora de Estudos e Projetos [FINEP])

# **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?

Participant information sheet

Participant information sheet 11/11/2025 No

Yes