ISRCTN37262487 https://doi.org/10.1186/ISRCTN37262487

# 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

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**
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

## Secondary study design
Randomised controlled trial

## Study setting(s)
Other

## Study type(s)
Treatment

## Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

## 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 µg) 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 measure
Frequency/intensity of adverse events during 30 days after vaccination.

### Secondary outcome measures
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

### Overall study start date
01/01/2009

### 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

### Age group
Adult

### Lower age limit
18 Years

### Upper age limit
50 Years

### Sex
Both

### Target number of participants
60

### 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)

### Sponsor details
Dr Akira Homma
Av. Brasil 4365
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21040-900

### Sponsor type

Industry

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

**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

**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