

# Immunogenicity and safety of a Meningococcus B Brazilian vaccine

<b>Submission date</b> 05/03/2009	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 27/03/2009	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 27/03/2009	<b>Condition category</b> Infections and Infestations	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

**Contact name**  
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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
ASCLIN/01/2009

## Study information

**Scientific Title**

Phase II/III immunogenicity and safety clinical trial of a Meningococcus B Brazilian vaccine

**Acronym**

MenB-Bio

**Study objectives**

Bio-Manguinhos meningococcus B vaccine (Men-B-Bio) is safe and immunogenic in children.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

National Ethics Committee approved on the 19th January 2009

**Study design**

Randomised open label four arm clinical trial

**Primary study design**

Interventional

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Hospital

**Study type(s)**

Treatment

**Participant information sheet**

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

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

Meningococcus B disease

**Interventions**

Randomised open-label study with four arms:

1. Men-B-Bio 12.5 µg
2. Men-B-Bio 25 µg
3. Men-B-Bio 50 µg
4. Similar Cuban vaccine (reference vaccine)

At the end of the study we expect to choose the best dose for the Brazilian vaccine.

Total duration: 20 months

Total duration of follow up: 20 months

Blood samples: before 1st dose, before 3rd dose and 1 month after 3rd dose

The second (25 µg) and third (50 µg) concentration groups will start after completion of the first concentration (12.5 µg) evaluation, hence the extension of the study to 20 months of follow up.

**Intervention Type**

Drug

**Phase**

Not Applicable

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

Bio-Manguinhos meningococcus B vaccine (Men-B-Bio)

**Primary outcome measure**

Seroconversion (bactericidal titre from seronegative to greater than or equal to 1/4 or four-fold increase in titre). Timepoints at the point of blood collection; before 1st dose, before 3rd dose and 1 month after 3rd dose.

**Secondary outcome measures**

Reactogenicity similar to the reference vaccine, measured 1 month of follow up after each dose for solicited events and for the entire study duration for all other events.

**Overall study start date**

01/05/2009

**Completion date**

31/12/2010

**Eligibility****Key inclusion criteria**

1. Both sexes
2. Aged between 4 years and 12 years
3. Agreement with Free and Informed Consent Form
4. Healthy children

**Participant type(s)**

Patient

**Age group**

Child

**Lower age limit**

4 Years

**Upper age limit**

12 Years

**Sex**

Both

**Target number of participants**

240

**Key exclusion criteria**

1. Personal history of meningitis or meningococcus B vaccine
2. Immunosuppression
3. Use of blood products in the last 12 months
4. Use of penicillin in the last 30 days
5. Personal history of serious adverse event to any vaccination

**Date of first enrolment**

01/05/2009

**Date of final enrolment**

31/12/2010

**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**

c/o Akira Homma

Av. Brasil 4365

Manguinhos

Rio de Janeiro

Brazil

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