

Immunogenicity and safety of a Meningococcus B Brazilian vaccine

Submission date 05/03/2009	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 27/03/2009	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 27/03/2009	Condition category 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