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Immunogenicity and safety of a Meningococcus B Brazilian vaccine

Submission date	Recruitment status	[X] Prospectively registered
05/03/2009	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
27/03/2009	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
27/03/2009	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

Protocol serial number
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

Study type(s)
Treatment

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(s)
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.

Key secondary outcome(s))
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.

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

Healthy volunteers allowed
No

Age group
Child

Lower age limit
4 years

Upper age limit
12 years

Sex
All

Key exclusion criteria
1. Personal history of meningitis or meningococcus B vaccine
2. Immunosupression
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)

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