

Safety and immunogenicity of meningococcus C conjugate vaccine

Submission date 02/12/2008	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 10/12/2008	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 10/12/2008	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

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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 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(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