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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
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