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Meningococcal C Conjugate Brazilian Vaccine Project

Submission date	Recruitment status	[_] Prospectively registered
18/11/2010	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
10/03/2011	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
10/03/2011	Infections and Infestations	[_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Mrs Tatiana Guimarães de Noronha

Contact details
Av. Brasil, 4365
Manguinhos
Rio de Janeiro
Brazil
21040-360
+55 21 3882 9479
tnoronha@bio.fiocruz.br

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
4670

Study information

Scientific Title
Immunogenicity and safety in children 1 - 9 years of a vaccine against meningococcal serogroup C strain 2135 produced with tetanus toxoid conjugate

Acronym
Meningococcal C Conjugate Vaccine Brazilian

Study objectives
This a non-inferiority study to test that the experiment vaccine confers the same amount of protection as the reference vaccine. Moreover, it is expected that the experiment vaccine is as safe as the reference vaccine.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Local ethics committee (Comitê de Ética em Pesquisa [CEP] ENSP) approved on the 3rd August 2010 (ref: 0139.0.031.000-10)

Study design
Single centre phase II randomised single-blind 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 the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Meningitis C

Interventions
The vaccine under test and the product used by the control group are intramuscular (deltoid muscle of the left arm) at a dose of 0.5 ml in a single application, in accordance with the standards of the Manual of Procedures of the Ministry of Vaccination Health (Ministry of Health, 2001).

We hope to add about 6 volunteers per day or approximately 120 volunteers per month. Each participant will have an estimated time to participate in the study of about two months which will include a total of four planned visits to the study site in addition to four telephone contacts with people involved in the project. Visits and contacts can be made in extraordinary case of any problem perceived by volunteers or by the study team.

Volunteer recruitment methods will be employed during the first contact with the volunteer in study, including information about the project. After assessing the eligibility criteria, will read the term of informed consent (TCLE). Only children whose parents/guardians sign the TCLE will be included in the study. We will carry out a small evaluation after presenting the TCLE, in order to ensure that all parents/guardians of children enrolled have understood what was explained. The ways in which the volunteer's response does not demonstrate full understanding will be explained a second time and the corresponding item of the assessment will be resubmitted. Will only be asked to sign the informed consent parents/guardians who demonstrate understanding of a minimum set of aspects of the study. The initial consultation (screening) will be to clarify about the project, reading/explanation of TC, the test pre-TCLE, and finally signing the TCLE if parents/guardians agree to participate.

After signing the TCLE will be made clinical evaluation on volunteers, even as part of the eligibility analysis of the likely participants. Children who meet the eligibility criteria will then be referred for vaccination.

Vaccines and diluents will be labelled for the clinical trial in the same way and the diluent to be coupled to the corresponding product. Due to the different presentation of the vaccine - the vaccine is lyophilised and must be diluted before application and the reference vaccine (Neisvac-C®) is already mounted in a syringe ready for use, the study will be the study will be single blind (or partially blind).

The volunteer, after collection of blood will be taken to vaccinate. If the participant fails to appear for the query on the appointed day, attempts will be made telephone calls to bring the volunteer to the study site. Phone calls will be given once a week to complete the last collection time for 30 days after vaccination.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Va-Mengoc.BC®, NeisVac®

Primary outcome measure
The immunogenicity of the vaccine under test seroconversion (from seronegative to seropositive) or 4-fold elevation of titres targeted bactericidal for the strain used and/or heterologous strain meningococcal C, compared to pre-vaccination titres. Measured through a blood sampling before vaccination and another 30 days after vaccination.

Secondary outcome measures
Total antibodies, measured by enzyme-linked immunosorbent assay (ELISA) through a blood sampling before vaccination and another 30 days after vaccination

Overall study start date
25/11/2010

Completion date
25/04/2011

Eligibility

Key inclusion criteria
1. Have 12 months of age less than 10 years and have not yet been vaccinated against meningitis C or B (Va-Mengoc.BC®)
2. Be accompanied by a parent or other custodian to confirm the ability and willingness to return to the clinic on the dates for the second and third visits
3. Be accompanied by a parent or other legal guardian who can provide the information necessary for the research team contact during follow-up
4. Be accompanied by a parent or other responsible person legally qualified to give informed consent to participate
5. Be users or siblings of children enrolled, in the health unit for routine immunisation or other medical care
6. Keep up with routine vaccines officially recommended for the first year of life in Brazil, except meningitis C vaccine and any type of flu shot within the 28 days preceding the vaccination study
7. Having good health, according to medical history, physical examination (documented as FRC) and review of the research team
8. Are not participating in any other clinical study

Participant type(s)
Patient

Age group
Child

Lower age limit
12 Months

Upper age limit
10 Years

Sex
Both

Target number of participants
360 children: 240 will receive the vaccine under test and 120 the vaccine NeisVac®

Key exclusion criteria
Not to be included, children whose legal guardians:
1. Cannot or do not wish to give their informed consent to participate
2. Cannot be contacted by phone (the phone itself or the house or neighbour) by the research team for monitoring adverse events and/or in the event of non-attendance at the second and third visits
3. Unable to complete the log of adverse events, measure and record the child's temperature,

measure the largest diameter of any adverse reactions at the injection site, or read and understand instructions or have other difficulties, according to the research team, justify the exclusion from the study
4. Are participating in another clinical study

Also not included are children who:
5. Have received another vaccine injections 30 days before the day of vaccination study or shall take such vaccines within 30 days after vaccination in the study. Vaccines programmed and not received before inclusion in this study can be administered after the last blood collection.
6. Have taken at least one dose of vaccine against meningitis C or BC (Cuban vaccine) in the past
7. Have received vaccinations, allergy-free injection in the last 14 days
8. Have had any type of meningitis
9. Have been treated with antibiotics in the last 10 days
10. Have been treated with benzathine penicillin in the last 30 days
11. Have fever on the first visit (greater than 37.5°C in the armpit) or 3 days earlier
12. Suffering from chronic disease
13. Had acute illness in the last 30 days
14. Have a history of anaphylaxis, asthma, urticaria or other allergic reaction to previous vaccinations or who have an allergy or hypersensitivity to vaccine components of the study
15. Have a history of severe asthma hospitalisation
16. Are receiving systemic therapy with high doses of steroids (e.g., 1 mg/kg/day of prednisone or equivalent), or have chronic use of inhaled corticosteroids, high power (e.g., 800 mg per day of fluticasone)
17. Have a diagnosed disorder haemophilia or any other disorder associated with prolonged bleeding
18. Have sickle cell anaemia
19. Have undergone splenectomy
20. Have a history of epilepsy, seizures or neurodevelopmental disorders such as autism
21. Have received blood, blood products or immunoglobulin preparations intravenously
22. Have any disorder, in the opinion of the investigator, may interfere with the evaluation of the objectives of the study

Date of first enrolment
25/11/2010

Date of final enrolment
25/04/2011

Locations

Countries of recruitment
Brazil

Study participating centre
Av. Brasil, 4365
Rio de Janeiro
Brazil
21040-360

Sponsor information

Organisation
The Immunobiological Technology Institute (Bio-Manguinhos) (Brazil)

Sponsor details
Avenida Brazil, 4365
Manguinhos
Rio de Janeiro
Brazil
21040-360
+55 21 3882 9479
tnoronha@bio.fiocruz.br

Sponsor type
Research organisation

Website
http://www.bio.fioruz.br

ROR
https://ror.org/04jhswv08

Funder(s)

Funder type
Research organisation

Funder Name
Bio-Manguinhos/Fiocruz (Brazil)

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