

Yellow fever vaccine dose-response study on children

Submission date 27/04/2011	Recruitment status No longer recruiting	☐ Prospectively registered
		☐ Protocol
Registration date 20/06/2011	Overall study status Completed	☐ Statistical analysis plan
		☐ Results
Last Edited 20/06/2011	Condition category Infections and Infestations	☐ Individual participant data
		☐ 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 01-2011

Study information

Scientific Title
Yellow fever vaccine dose-response study of 17-DD on children between 9 and 11 months of age: a double-blind randomised controlled trial

Study objectives

Yellow fever vaccine at lower doses is effective and safe in children between 9 and 11 months of age

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics Committee of Centre for Biological and Health Sciences (Centro de Ciências Biológicas e da Saúde) (CCBS) approved on 30th March 2011 (Protocol: 17/2011)

Primary study design

Interventional

Study design

Double-blind randomised controlled trial

Study type(s)

Prevention

Health condition(s) or problem(s) studied

Yellow Fever

Interventions

Vaccination with one dose subcutaneously (sc) of yellow fever vaccine in current use or in five decreasing dilutions, and a placebo (placebo will receive vaccine as soon as possible):

Arm 1: Reference vaccine (in current use): approximately 60,000 plaque-forming units (PFU), no protamine sulfate addition [approximately 12,000, 50% mouse lethal dose (MLD50)]

Arm 2: approximately 60,000 PFU with protamine sulfate addition (approximately 12,000 MLD50)

Arm 3: approximately 20,000 PFU, no protamine sulfate addition (approximately 4,000 MLD50)

Arm 4: approximately 20,000 PFU with protamine sulfate addition (approximately 4,000 MLD50)

Arm 5: approximately 6,000 PFU, no protamine sulfate addition (approximately 1,200 MLD50)

Arm 6: approximately 6,000 PFU with protamine sulfate addition (approximately 1,200 MLD50)

Volunteers will be followed up for a month after vaccination and 9 to 15 months after vaccination there will be another blood collection, for evaluation of duration of immunity.

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Yellow fever vaccine

Primary outcome(s)

To evaluate the immunogenicity of yellow fever vaccine used in decreasing doses and with addition of a purification step in the process of vaccine producing in children 9-11 months of age in relation to the formulation currently used.

It will be measured by blood samples 30 days after vaccination and serum antibodies before and after vaccination

Key secondary outcome(s)

1. Reactogenicity
2. Frequency of viraemia measured 5 days after vaccination
3. Duration of immunity measured one year later (9 - 15 months is acceptable) after vaccination

Completion date

31/08/2012

Eligibility

Key inclusion criteria

1. Healthy children, aged 9 - 11 months old
2. Guardians agree to participate after reading and understanding free and informed consent form

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Neonate

Sex

All

Key exclusion criteria

1. Prior vaccination against yellow fever
2. Use of immunosuppressor drugs in the last 12 months
3. Personal history of autoimmune diseases
4. Personal history of thymus diseases
5. Personal history of anaphylactic reactions to foods, drugs or vaccines
6. Personal history of allergy to eggs, erythromycin, canamycin or gelatin
7. Persons who received immunoglobulin, blood transfusions or blood derivatives in the last 12 months
8. Persons who received live virus vaccines in the last 30 days or who plan to receive them in the following 30 days after yellow fever vaccination
9. Acute febrile disease with an impaired general condition on time of vaccination
10. Metabolic diseases or metabolism inborn errors
11. Personal history of primary acquired immunodeficiency
12. Personal history of neoplasia (on treatment)

Date of first enrolment

01/06/2011

Date of final enrolment

31/08/2012

Locations

Countries of recruitment

Brazil

Study participating centre

Avenida Brasil

Rio de Janeiro

Brazil

21040-360

Sponsor information

Organisation

Bio-Manguinhos/Fiocruz (Brazil)

ROR

<https://ror.org/05gj5j117>

Funder(s)

Funder type

Government

Funder Name

Foundation for Scientific and Technological Development in Health (Fundação para o Desenvolvimento Científico e Tecnológico em Saúde [FIOTEC])/Oswaldo Cruz Foundation (Fundacio Oswaldo Crux [Fiocruz]) (Brazil)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration