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Yellow fever vaccine dose-response study on children

Submission date	Recruitment status	[_] Prospectively registered
27/04/2011	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
20/06/2011	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
20/06/2011	Infections and Infestations	[_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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)

Study design
Double-blind randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Prevention

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
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 wtih 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 measure
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

Secondary outcome measures
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

Overall study start date
01/06/2011

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

Age group
Neonate

Sex
Both

Target number of participants
1800

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)

Sponsor details
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Sponsor type

Industry

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

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