# Yellow fever vaccine dose-response study

Submission date	<b>Recruitment status</b> No longer recruiting	[X] Prospectively registered	
28/11/2008		☐ Protocol	
Registration date 03/12/2008	Overall study status Completed	Statistical analysis plan	
		[X] Results	
<b>Last Edited</b> 06/02/2013	Condition category Infections and Infestations	Individual participant data	

## Plain English summary of protocol

Not provided at time of registration

## Contact information

## Type(s)

Scientific

#### Contact name

Dr Reinaldo Martins

#### Contact details

Av. Brasil 4365 Manguinhos Rio de Janeiro Brazil 21040-900

## Additional identifiers

**EudraCT/CTIS** number

**IRAS** number

ClinicalTrials.gov number

Secondary identifying numbers

Asclin/003/2008

## Study information

#### Scientific Title

Dose-response study of 17DD yellow fever vaccine produced by Bio-Manguinhos/Fiocruz

## **Study objectives**

Yellow fever vaccine on lower doses is effective and safe.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Ethics Committee of Instituto de Pesquisa Clínica Evandro Chagas gave approval on the 10th November 2008 (ref: 0038.0.009.000-08)

## Study design

Double-blind randomised controlled trial

## 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

Yellow fever vaccination

#### **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):

Reference vaccine (in current use): approximately 60,000 PFU (approximately 12,000 MLD50)

Arm 1: approximately 20,000 PFU (approximately 4,000 MLD50)

Arm 2: approximately 6,667 PFU (approximately 1,300 MLD50)

Arm 3: approximately 2,222 PFU (approximately 450 MLD50)

Arm 4: approximately 740 PFU (approximately 150 MLD50)

Arm 5: approximately 246 PFU (approximately 50 MLD50)

Arm 6: placebo

Those who do not become protected by vaccination and the placebo group will receive one dose of the reference vaccine. Volunteers will be followed up for a month after vaccination. One year after vaccination there will be another blood collection, for evaluation of duration of immunity.

### Intervention Type

Drug

#### Phase

**Not Specified** 

## Drug/device/biological/vaccine name(s)

17DD yellow fever vaccine

#### Primary outcome measure

Neutralising antibodies: seroconversion and titre, during 30 days after vaccination

### Secondary outcome measures

- 1. Reactogenicity, measured with blood chemistry before vaccination, 5 days and 30 days after vaccination
- 2. Frequency of viraemia, evaluated 5 days after vaccination
- 3. Duration of immunity, measured 30 days after vaccination and one year later (9 15 months is acceptable)

## Overall study start date

01/03/2009

### Completion date

01/09/2010

## Eligibility

## Key inclusion criteria

- 1. Adult men
- 2. Aged 18 30 years old
- 3. Healthy
- 4. Agree to participate after reading and understanding Free and Informed Consent Form

## Participant type(s)

**Patient** 

## Age group

Adult

### Lower age limit

18 Years

#### Upper age limit

30 Years

#### Sex

Male

## Target number of participants

1050

#### Key exclusion criteria

- 1. Prior vaccination against yellow fever
- 2. Female
- 3. Use of immunosuppressor drugs in the last 12 months
- 4. Personal history of autoimmune diseases
- 5. Personal history of thymus diseases
- 6. Personal history of anaphylactic reactions to foods, drugs or vaccines
- 7. Personal history of allergy to eggs, erythromycin, canamycin or gelatin
- 8. Persons who received immunoglobulin, blood transfusions or blood derivatives in the last 12 months
- 9. Persons who received live virus vaccines or cholera vaccine in the last 30 days or who plan to receive them in the following 30 days after yellow fever vaccination

## Date of first enrolment

01/03/2009

## Date of final enrolment

01/09/2010

## 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

Av. Brasil 4365 Manguinhos Rio de Janeiro Brazil 21040-900

#### Sponsor type

Research organisation

### Website

http://www.fiocruz.br/

#### **ROR**

https://ror.org/05gj5j117

## Funder(s)

## Funder type

Research organisation

#### **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

## **Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/04/2013		Yes	No