ISRCTN38082350 https://doi.org/10.1186/ISRCTN38082350

# Yellow fever vaccine dose-response study

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

**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 |