ISRCTN72367932 https://doi.org/10.1186/ISRCTN72367932

# Multicentre, randomised, double-blind trial comparing yellow fever vaccines from 17D and WHO 17DD-213/77 substrains in children

| Submission date | Recruitment status | [_] Prospectively registered |
|---|---|---|
| 13/01/2006 | No longer recruiting | [_] Protocol |
| **Registration date** | **Overall study status** | [_] Statistical analysis plan |
| 03/02/2006 | Completed | [X] Results |
| **Last Edited** | **Condition category** | [_] Individual participant data |
| 02/11/2015 | Infections and Infestations | |

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

**Contact name**
Dr Luiz Antonio Camacho

**Contact details**
1480 Rua Leopoldo Bulhões
Sala 820
Prédio Ernani Braga
Manguinhos
Rio de Janeiro
Brazil
21041-210

## Additional identifiers

**Protocol serial number**
479663/2004-1 (CNPq)

## Study information

**Scientific Title**

Multicentre, randomised, double-blind trial comparing yellow fever vaccines from 17D and WHO 17DD-213/77 substrains in children

## Study objectives
Yellow fever is a severe mosquito-borne viral hemorrhagic disease, which may cause hepatitis, renal failure and shock. It is endemic in tropical areas of South America and Africa, where epidemics also occur. Vaccination is the only effective means of control. Safe and efficacious vaccines have been available for decades. Seroconversion rates in infants (about 80%) have been reported to be lower than in older children and adults (>95%).

Hypothesis:
That yellow fever vaccines prepared from 17DD and World Health Organization (WHO) 17D-213 /77 inducing similar antibody response in individuals below two years of age are similar. Maternal immunity and simultaneous immunisation with other attenuated vaccines affect seroconversion of infants by yellow fever vaccine.

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
Approved by the research ethics committee of the Oswaldo Cruz Foundation on 16 February 2005 (number 236A/03)

## Primary study design
Interventional

## Study design
Randomised, double-blind trial

## Study type(s)
Prevention

## Health condition(s) or problem(s) studied
Yellow fever

## Interventions
Two groups (allocation ratio 1:1) will be compared:
1. 17DD yellow fever vaccine, which is currently used for routine immunisation of residents and travellers to endemic areas in Brazil
2. A vaccine prepared with the WHO 17D-213/77 substrain especially for the trial, using the same process except for the vaccine virus

Both vaccines are manufactured by Bio-Manguinhos, Fiocruz (Rio de Janeiro, Brazil).

## Intervention Type
Drug

## Phase
Not Specified

### Drug/device/biological/vaccine name(s)
17D substrain of yellow fever and 17 WHO-213/77 substrain of yellow fever

### Primary outcome(s)
Seroconversion from non-responder (before vaccination) to patients exhibiting response or a four-fold increase in yellow fever antibody titers after vaccination.

### Key secondary outcome(s)
1. Adverse events within 30 days of immunisation
2. Seroconversion for measles, rubella and mumps

### Completion date
31/08/2006

## Eligibility

### Key inclusion criteria
Children aged between 9 and 23 months, brought by their guardians to public health care units in regions where vaccination against yellow fever is recommended by the Brazilian National Program of Immunisation

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Child

### Lower age limit
9 Months

### Upper age limit
23 Months

### Sex
All

### Key exclusion criteria
1. Severe malnutrition
2. Transitory or permanent immunodeficiency
3. Treatment with immunoglobulin or blood products
4. Administration of experimental drugs or vaccines in the previous 60 days or next 60 days of yellow fever vaccination
5. Hypersensitivity to chicken egg products or gelatin
6. Chronic or acute conditions constituting temporary contraindications to routine
7. Immunisation
8. Fever above 37.5°C
9. Mothers unwilling or unable to return 30 days after vaccination for blood collection

**Date of first enrolment**
01/02/2006

**Date of final enrolment**
31/08/2006

# Locations

**Countries of recruitment**
Brazil

**Study participating centre**
**1480 Rua Leopoldo Bulhões**
Rio de Janeiro
Brazil
21041-210

# Sponsor information

**Organisation**
Bio-Manguinhos (Brazil)

**ROR**
https://ror.org/05gj5j117

# Funder(s)

**Funder type**
Government

**Funder Name**
Brazilian Ministry of Health (Brazil) (Protocol number: 25386.001044/2004-32)

**Funder Name**
The National Council of Scientific and Technologic Development (CNPq) (Brazil) (Protocol number: 479663/2004-1)

**Funder Name**
Oswaldo Cruz Foundation (Brazil)

# Results and Publications

## 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 | 01/09/2015 | | Yes | No |