

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

Submission date
13/01/2006

Recruitment status
No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date
03/02/2006

Overall study status
Completed

☐ Statistical analysis plan

☒ Results

Last Edited
02/11/2015

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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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)

Study design

Randomised, double-blind trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Prevention

Participant information sheet

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 measure

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

Secondary outcome measures

1. Adverse events within 30 days of immunisation
2. Seroconversion for measles, rubella and mumps

Overall study start date

01/02/2006

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

Age group

Child

Lower age limit

9 Months

Upper age limit

23 Months

Sex

Both

Target number of participants

3500

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)

Sponsor details

4365 Av. Brasil

Pavilhão Rocha Lima

Manguinhos

Rio de Janeiro

Brazil

21040-900

Sponsor type

Industry

Website

<http://www.bio.fiocruz.br>

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

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	01/09/2015		Yes	No