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

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
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