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

Yellow fever vaccine dose-response study

Submission date
28/11/2008

Recruitment status
No longer recruiting

Registration date
03/12/2008

Overall study status
Completed

Last Edited
06/02/2013

Condition category
Infections and Infestations

[X] Prospectively registered

[_] Protocol

[_] Statistical analysis plan

[X] Results

[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Study type(s)
Treatment

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

Key secondary outcome(s))
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)

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
30 years

Sex
Male

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)

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

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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes