

Brazilian pentavalent vaccine

Submission date 25/06/2008	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 30/06/2008	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 30/06/2008	Condition category Infections and Infestations	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr Luiz Antônio Bastos Camacho

Contact details

Rua Leopoldo Bulhões 1480/820

Manguinhos

Rio de Janeiro

Brazil

21041-210

+55 21 2598 2630

luiz.camacho@ensp.fiocruz.br

Additional identifiers

Protocol serial number

ASCLIN/001/2007

Study information

Scientific Title

Immunogenicity and safety of Brazilian combined vaccine against diphtheria, tetanus, pertussis, haemophilus influenzae type B and hepatitis B (DTPw/HB/hib)

Study objectives

The Brazilian combined diphtheria, tetanus, pertussis, haemophilus influenzae type B and hepatitis B (DTPw/HB/hib) vaccine is as immunogenic and safe as the current DTPw/Hib and HB vaccines administered separately.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from the Fiocruz Ethics Committee on the 14th January 2007 (ref: 400/07).

Study design

Multicentre, non-inferiority randomised controlled trial, partially blinded.

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Diphtheria, tetanus, pertussis, hepatitis B and haemophilus influenzae type B diseases

Interventions

1. Experimental group: vaccine (DTPw/HB/Hib) at 2, 4 and 6 months of age
2. Control group: DTPw/Hib and HB vaccines in concomitant injections at different sites

Both groups will receive HB vaccine at birth.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Combined diphtheria, tetanus, pertussis, haemophilus influenzae type B and hepatitis B (DTPw/HB/hib) vaccine, DTPw/Hib vaccine, HB vaccine

Primary outcome(s)

Antibody titres to diphtheria, tetanus, pertussis, haemophilus influenzae (PRP) and hepatitis B, and seroprotection rate, measured after third dose, should be non-inferior to that from the reference vaccines (DTP/Hib and HB vaccines given separately).

Key secondary outcome(s)

1. Adverse event after each dose should be equivalent to reference vaccines
2. Consistency of production evaluated by equivalence in immunogenicity and safety of three lots of the experimental vaccine DTPw/HB/Hib

Completion date

30/09/2009

Eligibility

Key inclusion criteria

Healthy newborns (newborns and infants up to 7 months of age, of both sexes) whose parents /tutors understand the risk and benefits of the trial and agree to participate with written and informed consent.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Child

Upper age limit

7 months

Sex

All

Key exclusion criteria

Newborns or mothers:

1. Hepatitis B surface antigen (HBsAg) positive
2. Human immunodeficiency virus (HIV) seropositive
3. With positive serology for syphilis

Date of first enrolment

17/03/2008

Date of final enrolment

30/09/2009

Locations

Countries of recruitment

Brazil

Study participating centre

Rua Leopoldo Bulhões 1480/820

Rio de Janeiro

Brazil

21041-210

Sponsor information

Organisation

Bio-Manguinhos/Fiocruz (Brazil)

ROR

<https://ror.org/05gj5j117>

Funder(s)

Funder type

Government

Funder Name

Brazilian Ministry of Health (Brazil)

Funder Name

Brazilian Ministry of Science and Technology (Brazil)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration