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Brazilian pentavalent vaccine

Submission date	Recruitment status	[_] Prospectively registered
25/06/2008	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
30/06/2008	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
30/06/2008	Infections and Infestations	[_] Record updated in last year

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
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

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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

Secondary outcome measures
1. Adverse event after each dose shoud 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

Overall study start date
17/03/2008

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

Age group
Child

Upper age limit
7 Months

Sex
Both

Target number of participants
1200 volunteers

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 Leoplodo Bulhões 1480/820
Rio de Janeiro
Brazil
21041-210

Sponsor information

Organisation
Bio-Manguinhos/Fiocruz (Brazil)

Sponsor details
c/o Akira Homma
Director
Avenida Brasil 4365
Manguinhos
Rio de Janeiro
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21040-900

Sponsor type
Research organisation

Website
http://www.bio.fiocruz.br

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

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