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Immunogenicity and safety of combined vaccine against diphtheria, tetanus, pertussis and haemophilus influenzae type B: clinical validation of a product totally produced in Brazil

Submission date
16/02/2006

Recruitment status
No longer recruiting

Registration date
16/03/2006

Overall study status
Completed

Last Edited
04/06/2019

Condition category
Infections and Infestations

[_] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

ANVISA nr. 25351.086984/05-71

Study information

Scientific Title
Immunogenicity and safety of combined vaccine against diphtheria, tetanus, pertussis and haemophilus influenzae type B: clinical validation of a product totally produced in Brazil

Study objectives
The Brazilian vaccine is equivalent to Glaxosmithkline (GSK) vaccine.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the National Ethics Committee of the Ministry of Health on the 24th May 2005 (ref: 11.501).

Study design
Double blind, randomised, controlled 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
Diphtheria, tetanus, pertussis, haemophilus influenzae type B

Interventions
Three doses of Brazilian vaccines versus one dose of GSK vaccine

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Vaccine against diphtheria, tetanus, pertussis and haemophilus influenzae type B

Primary outcome measure
Polyribosil Ribitol Phosphate (PRP) titres and seroprotection after third dose should be equivalent to GSK vaccine.

Secondary outcome measures
1. Adverse event after each dose should be equivalent to GSK vaccine
2. Titres and seroprotection after second dose should be equivalent to GSK vaccine

Overall study start date
03/01/2006

Completion date
03/03/2007

Eligibility

Key inclusion criteria
Healthy children from two to six months of age

Participant type(s)
Patient

Age group
Child

Lower age limit
2 Months

Upper age limit
6 Months

Sex
Both

Target number of participants
1000

Total final enrolment
1000

Key exclusion criteria
1. Unhealthy children
2. Previous vaccination
3. Immunodeficiency

Date of first enrolment
03/01/2006

Date of final enrolment
03/03/2007

Locations

Countries of recruitment
Brazil

Study participating centre
Av Brasil 4365
Rio de Janeiro
Brazil
CEP 21040-900

Sponsor information

Organisation
Bio-Manguinhos/Fiocruz (Brazil)

Sponsor details
Av. Brasil 4365
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Sponsor type
Industry

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

ROR
https://ror.org/05gj5j117

Funder(s)

Funder type
Industry

Funder Name
Bio-Manguinhos/Fiocruz (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	01/11/2008	04/06/2019	Yes	No