

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	☐ Prospectively registered
Registration date 16/03/2006	Overall study status Completed	☐ Protocol
Last Edited 04/06/2019	Condition category Infections and Infestations	☐ Statistical analysis plan
		☒ Results
		☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

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).

Primary study design

Interventional

Study design

Double blind, randomised, controlled trial

Study type(s)

Prevention

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(s)

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

Key secondary outcome(s)

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

Completion date

03/03/2007

Eligibility

Key inclusion criteria

Healthy children from two to six months of age

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Child

Lower age limit

2 Months

Upper age limit

6 Months

Sex

All

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)

ROR

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

Funder(s)**Funder type**

Industry

Funder Name

Bio-Manguinhos/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	01/11/2008	04/06/2019	Yes	No