

# Randomized Clinical Trial to evaluate the Immunogenicity and Reactogenicity of the Brazilian Hepatitis B Vaccine (Butang®) in Infants using the Ventrogluteal area as an alternative intramuscular injection site

**Submission date**

30/05/2007

**Recruitment status**

No longer recruiting

☐ Prospectively registered

☐ Protocol

**Registration date**

04/07/2007

**Overall study status**

Completed

☐ Statistical analysis plan

☒ Results

**Last Edited**

10/05/2019

**Condition category**

Infections and Infestations

☐ 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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**Contact details**

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74605-080

## Additional identifiers

**Protocol serial number**

SAPP 16625

## Study information

**Scientific Title**

Randomized Clinical Trial to evaluate the Immunogenicity and Reactogenicity of the Brazilian Hepatitis B Vaccine (Butang®) in Infants using the Ventrogluteal area as an alternative intramuscular injection site

**Acronym**

RCT IR HBV IVG

**Study objectives**

Hepatitis B vaccine administered into ventrogluteal area induces similar immune response to anterolateral thigh injection in infants.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Local ethics committee of Maternal/Infant Hospital, Secretary of Health of Goiás (Hospital Materno-Infantil, Secretaria Estadual de Saúde de Goiás, Brazil) approved on 6th October 2006 (ref: CEP-HMI n. 11/06)

**Study design**

Randomised controlled trial

**Primary study design**

Interventional

**Study type(s)**

Prevention

**Health condition(s) or problem(s) studied**

Hepatitis B vaccine

**Interventions**

All infants will receive hepatitis B vaccine by intramuscular route.

First dose

Group 1: Hepatitis B vaccine (10 µg) into ventrogluteal area

Group 2: Hepatitis B vaccination (10 µg) into anterolateral thigh

Second dose (administered 30 days after the first dose)

Group 1: Hepatitis B vaccine (10 µg) into ventrogluteal area

Group 2: Hepatitis B vaccination (10 µg) into anterolateral thigh

Third dose (administered 180 days after the first dose)

Group 1: Hepatitis B vaccine (10 µg) into ventrogluteal area

Group 2: Hepatitis B vaccination (10 µg) into anterolateral thigh

48 to 72 hours after each vaccine dose, infants will be evaluated in order to detect local (pain, redness, swelling) or systemic (fever, urticaria, persistent crying / screaming) adverse events.

Blood samples (5 mL) will be collected 45 days after third hepatitis B vaccine dose in all participants.

**Intervention Type**

Drug

**Phase**

Not Specified

**Drug/device/biological/vaccine name(s)**

Hepatitis B vaccine

**Primary outcome(s)**

Immunogenicity, assessed using blood samples collected 45 days after the third dose.

**Key secondary outcome(s)**

Reactogenicity, assessed 48-72 hours after each vaccine dose. These will be scored on visual scales (0: no reaction to 5: highest level of reaction).

**Completion date**

01/08/2008

**Eligibility****Key inclusion criteria**

1. Newborn
2. Birth weight of more than or equal to 2.5 kg
3. In good health

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Neonate

**Sex**

All

**Total final enrolment**

580

**Key exclusion criteria**

1. Previous hepatitis B vaccination
2. Mother Hepatitis B Virus (HBV) and/or HIV positive

3. History of blood or immunoglobulin transfusion
4. Any condition which, in the opinion of the investigator, may interfere in the evaluation of the objectives of the study

**Date of first enrolment**

01/07/2007

**Date of final enrolment**

01/08/2008

## Locations

**Countries of recruitment**

Brazil

**Study participating centre**

Rua 227 Qd 68

Goiânia

Brazil

74605-080

## Sponsor information

**Organisation**

Federal University of Goiás (Universidade Federal de Goiás) (Brazil)

**ROR**

<https://ror.org/0039d5757>

## Funder(s)

**Funder type**

Government

**Funder Name**

The National Council for Scientific and Technological Development (Conselho Nacional de Pesquisa) (CNPq) (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?
<a href="#">Results article</a>	results	01/09/2010	10/05/2019	Yes	No