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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	Recruitment status	[_] Prospectively registered
30/05/2007	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
04/07/2007	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
10/05/2019	Infections and Infestations	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Sheila Araujo Teles

Contact details
Rua 227 Qd 68
S/N - Setor Leste Universitário
Goiânia
Brazil
74605-080

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

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

Secondary outcome measures
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).

Overall study start date
01/07/2007

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

Age group
Neonate

Sex
Both

Target number of participants
560

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)

Sponsor details
Câmpus Samambaia (Câmpus II)
Prédio da Reitoria
Caixa Postal 131

Goiânia
Goiás
Brazil
74001-970

Sponsor type
University/education

Website
Http://www.ufg.br

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

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	01/09/2010	10/05/2019	Yes	No