

Evaluation of hepatitis B vaccine adherence among transgender women

Submission date 19/08/2022	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 24/08/2022	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 29/12/2023	Condition category Other	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

The Brazilian health surveillance system does not collect data on gender identity. Studies on viral hepatitis among trans gender women (TGW) are scarce, and there is no data on hepatitis B vaccination. Therefore, this study aimed to estimate the prevalence of hepatitis A, B, and C among TGW in Central Brazil. In addition, we compared the adherence and immunogenicity of two hepatitis B vaccine schedules to contribute to public health for this socially marginalized population.

The purpose of this study was to estimate the prevalence of viral hepatitis A, B, and C in three cities in Goiás (goiânia, Itumbiara e Jataí), Central Brazil, and compare the adherence and immunogenicity of two hepatitis B vaccine schedules among transgender women (TGW) in Goiânia.

Who can participate?

Persons who self-defined as transgender women and presented a valid RDS coupon and report no hepatitis B vaccine doses previously or don't know her vaccine status.

What does the study involve?

A total of 440 participants were interviewed and tested for hepatitis A virus, hepatitis B virus, and hepatitis C virus markers during 2017-2018. Of 285 TWG recruited in Goiânia, 230 denied previous hepatitis B vaccine and were invited and accepted to receive hepatitis B vaccine doses. They were randomized to receive a super accelerated hepatitis B vaccine schedule (G1) vs. a standard schedule (G2). The adherence and immunogenicity of hepatitis B vaccine were evaluated among women who received at least three vaccine doses.

What are the possible benefits and risks of participating?

Benefits: being vaccinated against hepatitis B and thus being immunized against this infection that causes a disease of high morbidity and mortality.

Risks: the hepatitis B vaccine has been available in Brazil since the late 1990s and is offered free to the entire population. Its effectiveness is widely known. However, the interval between doses has been a problem for the completeness of the regimen, and several accelerated regimens have been tested and proposed, as in this study. Therefore, the risks of participating in this study

are low and the same as if they had been vaccinated in public or private immunization services and limited to local adverse reactions such as pain and swelling at the injection site and systemic reactions such as fever (the most common) and allergic reactions.

Where is the study run from?

Fundação de Amparo a Pesquisa do Estado de Goiás (FAPEG) (Brazil)

When is the study starting and how long is it expected to run for?

March 2017 to January 2020

Who is funding the study?

Fundação de Amparo a Pesquisa do Estado de Goiás (FAPEG) (Brazil)

Who is the main contact?

Sheila A. Teles, sateles@ufg.br

Contact information

Type(s)

Principal investigator

Contact name

Prof Sheila Araujo Teles

ORCID ID

<https://orcid.org/0000-0002-7059-4241>

Contact details

Rua T 38, n. 1097 apto 201

Goiânia

Brazil

74223042

+55-62999215006

sateles@ufg.br

Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

77481417.5.0000.5083, 201.710.267.000.536

Study information

Scientific Title

Viral hepatitis A, B and C in a group of transgender women in Central Brazil

Study objectives

A higher adherence to hepatitis B vaccine dose using a super accelerated scheme when compared to the conventional scheme

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 17/10/2018, Ethics Committee for Human Research of the Universidade Federal de Goiás (Prédio da Reitoria Térreo Cx. Postal 131, Campus Samambaia. 74.001-970. Brazil; +55-62-35211215; cep.prpi.ufg@gmail.com), ref: 77481417.5.0000.5083

Study design

Interventional randomized parallel trial

Primary study design

Interventional

Study type(s)

Prevention

Health condition(s) or problem(s) studied

Adherence to hepatitis B vaccine doses in healthy transgender women (TGW)

Interventions

The study included 230 TGW who reported no previous hepatitis B or were unaware of their hepatitis B vaccination status in a hepatitis B vaccination cohort. They were randomly recruited to receive either a super accelerated scheme (G1; four doses at 0, 7, 21, and 180 days) or a standard scheme (G2; three doses at 0, 1, and 4 months). Vaccine doses of 20 µg of recombinant HBsAg were administered into the deltoid muscle (Serum Institute of India PVT. LTD; lots 03560L24 and 03560L72).

Intervention Type

Biological/Vaccine

Phase

Phase III/IV

Drug/device/biological/vaccine name(s)

Hepatitis B vaccine. Serum Institute of India PVT. LTD; lots 03560L24 and 03560L72

Primary outcome(s)

Adherence to at least three vaccine doses measured using patient records.

Key secondary outcome(s)

Immunogenicity of hepatitis B vaccine measured using anti-HBs titer measure following the third and fourth vaccine doses.

Completion date

23/01/2020

Eligibility

Key inclusion criteria

1. Self-defined as transgender women
2. Present valid RDS coupon
3. Report no hepatitis B vaccine doses previously or don't know her vaccine status

Participant type(s)

Healthy volunteer

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

Total final enrolment

230

Key exclusion criteria

Persons who were found noticeably under the effects of psychoactive drugs (drunken and dopey) were excluded.

Date of first enrolment

25/04/2018

Date of final enrolment

27/08/2019

Locations

Countries of recruitment

Brazil

Study participating centre

Universidade Federal de Goiás

227 street, 68 square -Leste Universitário Sector

Goiânia

Brazil

74605-080

Sponsor information

Organisation

Fundação de Amparo a Pesquisa do Estado de Goiás

Funder(s)

Funder type

Government

Funder Name

Fundação de Amparo à Pesquisa do Estado de Goiás

Alternative Name(s)

Research Support Foundation of the State of Goiás, Foundation for Research Support of the State of Goiás, Goiás State Research Support Foundation, FAPEG

Funding Body Type

Government organisation

Funding Body Subtype

Local government

Location

Brazil

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during the current study will be published as a supplement to the subsequent results publication.

IPD sharing plan summary

Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		27/09/2023	29/12/2023	Yes	No
Participant information sheet			23/08/2022	No	Yes