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Evaluation of hepatitis B vaccine adherence among transgender women

Submission date
19/08/2022

Recruitment status
No longer recruiting

Registration date
24/08/2022

Overall study status
Completed

Last Edited
29/12/2023

Condition category
Other

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

Study website
https://

Contact information

Type(s)
Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Randomised parallel trial

Study setting(s)
Community

Study type(s)
Prevention

Participant information sheet
See additional files (in Portuguese)

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

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

Overall study start date
01/03/2017

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

Age group
Adult

Sex
Female

Target number of participants
285

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

Sponsor details
Rua Dona Maria Joana (travessa da AV. 83), 150
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Brazil
74.083-140
+55 (62) 3623-0400
atendimento.fapeg@goias.gov.br

Sponsor type
Government

Website
http://www.fapeg.go.gov.br/

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

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
30/10/2022

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?
Participant information sheet			23/08/2022	No	Yes
Results article		27/09/2023	29/12/2023	Yes	No