Plan Overview

A Data Management Plan created using DMPTool

Title: A case-control study to determine the effectiveness of a tetravalent dengue vaccine in the State of Paraná, Brazil

Creator: Expedito Luna - **ORCID:** 0000-0002-1145-9672

Affiliation: Universidade de São Paulo (www5.usp.br)

Funder: Sabin Vaccine Institute (sabin.org)

Funding opportunity number: 01/2017

Grant: 01/2017

Template: USP Template - Minimum

Project abstract:

Background: The Brazilian state of Paraná conducted a mass vaccination campaign against dengue with the tetravalent attenuated vaccine CYD-TDV. The campaign targeted thirty endemic municipalities. The objective of this study was to assess the effectiveness of CYD-TDV in preventing symptomatic virologically confirmed dengue cases according to specific age groups in five of the municipalities.

Methods: A case-control study was carried out in the five most populous municipalities targeted by the vaccination, with a vaccine uptake of 25%. Symptomatic dengue cases were identified by the municipal health departments. The age groups targeted were 15–18 and 19–27 in four municipalities and 9–14 and 28–44 in one municipality. All cases were confirmed by real time reverse transcription quantitative polymerase chain reaction (RT-qPCR). For each case, two controls were selected: a neighbourhood control and a workplace or school/college control, matched by age group. A conditional logistic regression model was used to determine the odds ratio for vaccination and the vaccine effectiveness.

Findings: Study participants included 618 RT-qPCR-confirmed dengue cases and 1,236 matched controls (with a non-reactive dengue IgM serologic test). Vaccine effectiveness against dengue due to any serotype was 11·1% (95% CI: –19·0%; 33·6%). Effectiveness against DENV-1 was 33·3% (95% CI: -5·0%; 57·6%) and against DENV-2 was -56·7% (95% CI: -142·2%; -5·0%). No DENV-3 was detected. The vaccine was significantly effective in the prevention of DENV-4 cases (VE = 93·3%; 95% CI: 47·7%; 99·2%).

Interpretation: CYD-TDV was effective in the prevention of symptomatic cases due to DENV-4, but not due to any serotype. The low dengue seroprevalence in the target population could possibly be related to these results.

Funding: This study was supported through a grant to the Sabin Vaccine Institute from Sanofi-Pasteur. Sanofi-Pasteur had no role in the study design, protocol development, data collection, analysis, or publication of results.

Start date: 08-01-2016

End date: 12-31-2021

Last modified: 05-10-2023

Copyright information:

A case-control study to determine the effectiveness of a tetravalent dengue vaccine in the State of Paraná, Brazil - Description of Data and Metadata produced by the project

Status of the participants: dengue case (with a confirmed PCR test) OR control (without signs or symptoms of dengue, and a negative IgM serologic test for dengue

Age

Sex

Dengue vaccination status: fully vaccinated (3 doses); incomplete vaccination (one or two doses); non-vaccinated

Participant previously reported as a dengue confirmed case (YES or NO)

The data were collected in interviews with the participants. Data on dengue diagnosis were retreived from the GAL (Gerenciador de Atividades Laboratoriais) plataform, run by the Ministry of Health. Data on dengue vaccine status were obtained from the vaccine registry of Secretaria Estadual de Saúde do Paraná (SESA-PR).

Planned Research Outputs

Estimates of the cyd-tvd vaccine effectiveness - "Effectiveness of CYD-TVD"

Effectiveness is obtained by the formula: 1 - OR

Data paper - "A case-control study to determine the effectiveness of a tetravalent dengue vaccine in the State of Paraná, Brazil"

The paper contains data on:

- Vaccine coverage

- Proportion of cases who were vaccinated against dengue

- Proportion of controls who were vaccinated against dengue

- Dengue Vaccine effectiveness estimates

Planned research output details

Title	Type	Anticipated release date	Initial access level	Intended repository(ies)	Anticipated file size	License	Metadata standard(s)	May contain sensitive data?	May contain PII?
Effectiveness of CYD-TVD	Estimates of the cyd-tvd vaccine effectiveness	2021-10-12	Restricted	None specified		None specified	None specified	No	No
A case-control study to determine the effectivenes ...	Data paper	2021-10-18	Open	INDEPTH Data Repository	1 MB	Creative Commons Attribution Non Commercial No Derivatives 4.0 International	MIBBI (Minimum Information for Biological and Biomedical Investigations)	No	No