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Prevalence of drug-resistant tuberculosis in Sinaloa Mexico

Submission date
21/07/2022

Recruitment status
No longer recruiting

Registration date
10/08/2022

Overall study status
Completed

Last Edited
25/04/2024

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English Summary
Background and study aims
Tuberculosis (TB) is a disease caused by Mycobacterium tuberculosis that has resulted in millions of deaths worldwide, especially in developing countries. Among the most important risk factors for the development of TB is infection with the human immunodeficiency virus (HIV) and type 2 diabetes mellitus (T2DM). However, the appearance of drug-resistant M tuberculosis (DR-MTB) strains has significantly complicated the prevention, control, and treatment actions of TB, becoming a threat to public health. In this regard, Sinaloa is a Northwest state in México, which has been identified as an endemic area for TB disease; notwithstanding, the prevalence is unknown, as well as the prevalence of DR-MTB in the HIV and T2DM populations. The objective of this study is to evaluate the prevalence of DR-MTB in patients with HIV or T2DM in Sinaloa, from the analysis of a database of the National Epidemiological Surveillance System (SINAVE) during the period 2019-2022.

Who can participate?
Patients aged between 18 and 85 years old with a positive diagnosis for pulmonary M tuberculosis in populations with HIV or T2DM, in which diagnosis was confirmed by the GeneXpert technique

What does the study involve?
This is not an interventional study and no clinical manipulation of patients is required. This cross-sectional and retrospective study will be involved the calculation of the prevalence of TB in HIV and T2DM groups, as well as the DR-MTB for rifampicin in both groups. Also, clinical, and demographic variables will be studied from the data recorded in the database of SINAVE.

What are the possible benefits and risks of participating?
Benefits for the health service system in an endemic state will be obtained to identify risk factors and best-clinical management in HIV and T2DM populations diagnosed with TB. There are no risks related to patients.

Where is the study run from?
This study is a collaboration of the Health Services of Sinaloa, the State Public Health Laboratory of Sinaloa Autonomous University of Sinaloa, Faculty of Biological Chemistry Sciences (Mexico)

When is the study starting and how long is it expected to run for?
January 2022 to January 2023

Who is funding the study?
National Council for Science and Technology Mexico (Consejo Nacional de Ciencia y Tecnología México) (Mexico)

Who is the main contact?
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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
Nil known

Study information

Scientific Title
Prevalence of rifampicin drug-resistant Mycobacterium tuberculosis in HIV and type 2 diabetic patients: A retrospective and cross-sectional study at endemic State Sinaloa Mexico

Study hypothesis
The prevalence of drug-resistant Mycobacterium tuberculosis (DR-MTB) in HIV and diabetic patients is higher compared with other groups affected by DR-MTB

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 31/05/2022, General Hospital of Culiacan Ethics Committee (Aldama & Nayarit street, Culiacan, Sinaloa, 80230, Mexico; +52-6677169810; conbioetica.contacto@salud.gob.mx); ref: 000901

Study design
Observational cross-sectional retrospective study

Primary study design
Observational

Secondary study design
Cross sectional study

Study setting(s)
Other

Study type(s)
Screening

Participant information sheet
No participant information sheet available

Condition
Prevalence of drug-resistant Mycobacterium tuberculosis (DR-MTB) in HIV and diabetic patients

Interventions
Data will be analysed from SINAVE, which integrates information from all over the country and from all the institutions of the National Health System (SNS). The information generated by SINAVE, is related to health, specific conditions, sociodemographic data, laboratory determination, geographical area, and previous or new pharmacological treatments, among others. The intervention of this database will be from January 2019 to February 2022 and limited to the Sinaloa State of Mexico.
The following characteristics of the patients registered in the clinical files that manage to meet all the inclusion criteria for this research study will be recorded and grouped, the variables to be evaluated will be the following: sex, age, weight, disease other than HIV or T2DM location of the disease, institution that provides care, form of diagnosis, smoking, alcoholism and drug addiction.
To calculate the prevalence of the disease, a record of the number of cases that occur in the population each year must be kept.
Clinical data from TB specimens that were positive at diagnosis using the GeneXpert MTB/RIF Dx System test version 4.7 will be analyzed.

Intervention Type
Other

Primary outcome measure
Prevalence of rifampicin drug-resistant Mycobacterium tuberculosis, determined by a positive diagnosis using the GeneXpert MTB/RIF Dx System test version 4.7, recorded in the SINAVE database between January 2019 and February 2022

Secondary outcome measures
Recorded in the SINAVE database between January 2019 and February 2022:
1. Prevalence of TB/HIV, the following information will be used: p= number of events with the disease/total recorded events
2. Prevalence of TB/T2DM, the following information will be used: p= number of events with the disease/total recorded events
3. Prevalence of TB/T2DM drug resistance to rifampicin, the following information will be used: p= number of events with the disease/total recorded events
4. The correlation between suffering from the disease, HIV or T2DM with the presence of DR-TB, the prevalence ratio will be obtained and subsequently the prevalence odds ratio
5. Sociodemographic variables such as sex, age, weight, disease other than HIV or T2DM location of the disease, institution that provides care, the form of diagnosis, smoking, alcoholism and drug addiction will be recorded from the clinical history obtained from the SINAVE database

Overall study start date
15/01/2022

Overall study end date
31/01/2023

Eligibility

Participant inclusion criteria

1. Aged between 18-85 years old
2. Populations with HIV or T2DM
3. Positive diagnosis in the state of Sinaloa in the period 2019-2021 of pulmonary Mycobacterium tuberculosis

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
85 Years

Sex
Both

Target number of participants
The total of clinical cases, n=25,985, captured into the Database of SINAVE from january 2019 to february 2022, 3602 positive cases were recorded

Total final enrolment
391

Participant exclusion criteria
1. Aged 17 years old and under
2. Aged 86 years old and over
3. Extrapulmonary Mycobacterium tuberculosis diagnosis
4. Diagnosis in the other States of México
5. Diagnosis prior to 2019 or after 15 February 2022
6. Clinical cases HIV-TB and T2DM-TB not diagnosed with GeneXpert technique

Recruitment start date
02/06/2022

Recruitment end date
31/12/2022

Locations

Countries of recruitment
Mexico

Study participating centre

State Public Health Laboratory of Sinaloa
Lola Beltran 3057
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Study participating centre
Autonomous University of Sinaloa, Faculty of Biological Chemistry Sciences
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Study participating centre
Health Services of Sinaloa
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Sponsor information

Organisation
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Sponsor type
Government

Website
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Funder(s)

Funder type
Government

Funder Name
Consejo Nacional de Ciencia y Tecnología

Alternative Name(s)
Consejo Nacional de Ciencia y Tecnología, National Council of Humanities, Sciences and Technologies, Mexican National Council of Science and Technology, National Council for Science and Technology (CONACyT), National Council of Science and Technology, Mexico, Conahcyt

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Mexico

Results and Publications

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

Intention to publish date
01/10/2023

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available as the SINAVE database is the property for the exclusive use of the National Epidemiological Surveillance System

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		22/04/2024	25/04/2024	Yes	No