

Notice

We are conducting research on the prevalence of tuberculosis in the Shinjuku area.

If you do not wish to become a subject of this study, you may opt out by contacting us. There is no disadvantage for not participating.

Study title: A Molecular and clinical epidemiological study of tuberculosis in Shinjuku, Tokyo area in Japan

Background: Tuberculosis (TB) is an important public health infectious disease caused by *Mycobacterium tuberculosis* (*M.tuberculosis*). The number of tuberculosis patients in Japan is decreasing year by year, but in recent years, with the increase in the number of people coming to Japan, foreign-born tuberculosis patients born are becoming more prominent. Molecular epidemiological survey is an epidemiological survey using bacterial gene information.

Purpose: we will study how tuberculosis epidemiology in the Shinjuku, Tokyo areas has changed over the past 20 years using molecular epidemiological analysis.

Method: We will use clinical information and strains of patients diagnosed and treated with tuberculosis in our hospital for research in a manner that the individuals cannot be identified . The DNA of *M. tuberculosis* will be extracted from the strain and the whole genome will be analyzed. The *M. tuberculosis* DNA will be provided to an external facility for analysis.

Eligible persons: Those who meet the following three conditions (1),(2),(3) OR (4)

(1) diagnosed or treated with tuberculosis at our hospital from January 2000 to 2019

(2) have tested positive for culture with *Mycobacterium tuberculosis*

(3) More than 10 years and Less than 30 differences

(4) diagnosed as TB, or started treatment, hospitalized, or introduced to our hospital for tuberculosis treatment in the representative year (2000, 2011, 2015, 2019)

* In addition to the above, there are some people who are not eligible for research according to the detailed regulations.

Period of data covered: January 2000 to December 2019

Research (planned) Period: President approval date - December 2025

Ethical matters: This is a retrospective observational study approved by our Ethics Committee. We report the status of conflicts of interest to the National Center of Global Health and Medicine (NCGM) Conflict of Interest Management Committee and manage it appropriately under their guidance. This study does not alter the content of medical care and participating in this study does not result in any medical disadvantage. Information on age, gender, nationality, comorbidities, blood test, radiological test and microbiological test results, treatment regimens, clinical course of the diseases, and the strains retained by the hospital shall be used. Information is not analyzed or published in a way that individuals can be identified. A participant can withdraw from the study without a penalty at any time by contacting the research team using the contact information below. We will respond to any request or inquiry related to the participation or non-participation of minors and those with impaired cognitive function, when submitted by a legally authorized representative. Information and study-related materials collected during the study can be accessed to the scope that does not interfere with personal information and the study.

Thank you very much for your understanding and cooperation in the study.

Contact information: National Center of Global Health and Medicine Department of Pulmonary Medicine

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