

## Notification of Our Clinical Study

# An Observational Study on Tuberculosis in Foreigners

Our Pulmonology Department is currently conducting a clinical study on tuberculosis in foreigners.

If you have any questions, please contact us.

Study Title: An Observational Study on Tuberculosis in Foreigners

**Background:** In Japan, approximately 20,000 individuals develop tuberculosis and require treatment every year. Many of them are elderly individuals aged 65 or older; however, the morbidity rate has been decreasing annually. In contrast, the number of cases of foreigners, particularly young individuals who come to Japan to study or work, developing tuberculosis, are becoming more noticeable. Tuberculosis diagnoses among foreigners are expected to increase in the future, and they represent a major challenge from the viewpoint of measures for combating this disease in Japan. The treatment of tuberculosis in foreigners is associated with difficulties that are not encountered with Japanese patients with tuberculosis, such as difficulty in communication because of a language barrier, an unstable financial and/or social background in many cases, a high rate of resistant tuberculosis, and elevated stress during inpatient treatment due to lifestyle differences, among others. Therefore, it is important to examine the clinical characteristics of foreigners with tuberculosis, issues associated with their treatment, and measures for addressing these issues; the outcomes of this study will be important for future medical care.

**Study Objective:** To examine the clinical characteristics, treatment details, issues associated with treatment surrounding the infection of tuberculosis patients of foreign nationality.

**Study Methods:** This is an observational study conducted at our hospital. The subjects are patients with tuberculosis who began undergoing an inpatient or outpatient treatment for tuberculosis between April 2010 and March 2016 (regardless of age). Their nationality, backgrounds, clinical characteristics, treatment, susceptibility test results and outcome are examined.

**Ethical Issues:** This was an observational study approved by our ethics committee. Because of the study design, the subjects' medical care and criteria for discharge do not change, and they do not have any medical disadvantage. All analyses are conducted with anonymized data. If requested, the subjects can access the study protocol and resources regarding the study methods, unless it compromised the personal information of the participants or the originality of this study. Subjects can also access, in a standardized format, their personal information that was collected. Individuals can be excluded from the study if they notified the physician in charge of their care. Non-participation in the study do not impart any particular disadvantage to the patients. In the case of a minor, we respond to any requests to exclude the participant from the study and/or inquiries from his/her guardian. We appreciate the patients' understanding of and cooperation in this study.

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