

Protocol of a Nationwide Observational Cohort Study for Long-Term Impacts on Lung Health and Life after Tuberculosis in Korea (LIFE-TB)

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Abstract

Background: Growing concern has emerged regarding the disease burden and long-term outcomes associated with post-tuberculosis lung disease (PTLD). This study is designed to assess the long-term effects of tuberculosis (TB) on lung health and quality of life, aiming to fill the critical evidence gap in PTLD research.

Methods: This investigation utilizes a nationwide, prospective, multicenter observational cohort design. Seven tertiary healthcare centers in Korea will recruit at least 350 participants in the treatment-phase group (with a minimum of 50 participants per site) between June 2025 and December 2026. Eligible participants are individuals aged ≥19 years who are either in the course of anti-TB treatment (treatment-phase group), or have previously completed treatment for pulmonary TB (post-treatment group). Exclusion criteria are diagnosis limited to extrapulmonary TB, age <19 years, or refusal to provide consent. Data will be gathered at baseline and annually for up to 5 years until December 2031. Baseline assessments will capture demographic characteristics, TB-related clinical history, relevant comorbidities, and medication use. Initial laboratory evaluations will cover blood analysis, urinalysis, and electrocardiographic measurements. Comprehensive clinical evaluations include symptom scoring, spirometry, chest imaging, and administration of quality of life questionnaires. Annual follow-up will involve repeating spirometry, chest imaging, and quality of life assessments. No additional interventions beyond routine clinical care will be mandated by the study protocol. All collected data will be anonymized and managed securely, adhering to both institutional and ethical regulatory standards (ClinicalTrials.gov: NCT06946784).

Conclusion: This will be the first nationwide observational cohort investigating PTLD in Korea, delivering key real-world evidence to inform national and international post-TB management policies.

Keywords: Post-tuberculosis Lung Disease; Prospective Observational Cohort; Protocol

Introduction

In 2020, it was estimated that approximately 155 million people worldwide were tuberculosis (TB) survivors, a number that surpasses the annual incidence of TB by more than 10-fold¹. Within this population, a significant proportion are anticipated to develop various health issues related to post-TB health conditions beyond the microbiologic cure, as TB frequently results in substantial structural impairment to the airways, lung parenchyma, pleura, and vasculature²⁻⁴. The term post-tuberculosis lung disease (PTLD) describes chronic structural or functional abnormalities of the respiratory system, symptomatic or asymptomatic, that are at least partially caused by a history of pulmonary TB^{2,3}.

Approximately half of individuals who have achieved cure from pulmonary TB experience persistent respiratory sequelae, such as chronic pulmonary diseases and progressive decline in lung function⁵. In addition to the pulmonary consequences, PTLD is linked to an increased risk of developing cardiovascular disease, and the long-term all-cause mortality rate is more than three times higher than that observed in the general population⁶. Furthermore, although the Republic of Korea has established a special copayment deduction program during TB treatment, a substantial number of individuals continue to encounter significant socioeconomic difficulties even after completing therapy⁷. Evidence from prior studies indicates that full recovery of socioeconomic status post-treatment is uncommon, probably due to the impact of comorbid chronic diseases and the ongoing financial challenges related to PTLD^{7,8}. Increasing recognition of PTLD's long-term complications has led the World Health Organization to emphasize the importance of addressing TB-related disabilities⁹. In Korea, the incidence of TB has consistently decreased over the past decade, with 19,540 TB cases (38.2 per 100,000 population) reported in 2023¹⁰. Given the ongoing reduction in TB incidence in Korea, there is an increasing need to incorporate PTLD monitoring and management into public health policies to provide sustained support for individuals previously affected by TB.

Despite its recognized clinical and public health significance, PTLD remains an area with limited research advancement, as evidenced by the first international symposium on PTLD convened only in August 2019². Korea does not yet have a nationwide prospective cohort dedicated to the systematic investigation of PTLD, highlighting a critical need for organized data collection and extended longitudinal research. Through this project, we propose to establish a prospective, multi-

center observational cohort comprising individuals in Korea who have a history of pulmonary TB.

Materials and Methods

1. Goals and objectives

The main goal of this prospective cohort study is to assemble a group of individuals diagnosed with pulmonary TB, accompanied by comprehensive clinical data, to facilitate the assessment of TB's long-term consequences on respiratory health and overall quality of life. The specific study objectives are: (1) to delineate the prevalence and progression of PTLD-related abnormalities and determine major factors associated with adverse clinical outcomes, and (2) to analyze temporal trends in pulmonary function, health-related quality of life, and healthcare service use patterns. The primary outcome of interest is the prevalence of PTLD, which is characterized by ongoing functional, radiologic, or symptomatic respiratory abnormalities at least partially attributable to previous pulmonary TB^{2,3}.

2. Study design and setting

Long-Term Impacts on Lung Health and LiFE after Tuberculosis in Korea (LIFE-TB) is a nationwide, prospective, multicenter observational cohort study enrolling individuals with TB in Korea. Between June 2025 and December 2026, seven tertiary healthcare centers participating in the public-private mix TB control project¹¹ will recruit at least 350 participants (a minimum of 50 from each site) who are either initiating or currently receiving anti-TB treatment. Written informed consent will be obtained from all participants prior to enrollment.

Study data will be obtained at baseline and periodically throughout a 5-year follow-up period extending until December 2031. Assessments will take place at baseline, 6 months, 1 year, and annually for as long as 6 years, thereby ensuring a minimum of 5 years of follow-up after treatment completion. If the sample size is inadequate at the anticipated time point, study duration may be extended at the discretion of the investigators following further discussion.

The participating institutions are Chonnam National University Hospital, Hallym University Dongtan Sacred Heart Hospital, Incheon St. Mary's Hospital, Pusan National University Hospital, Pusan National University Yangsan Hospital, Seoul St. Mary's Hospital, and Severance Hospital (listed in alphabetical order). Additional sites may be added after protocol publication.

3. Study participants

The inclusion criteria are: (1) age 19 years or older; (2) a confirmed diagnosis of pulmonary TB; and (3) currently receiving anti-TB treatment or a history of anti-TB treatment within the previous 5 years. The exclusion criteria are: (1) age under 19 years; (2) extrapulmonary TB without pulmonary involvement; (3) declining to provide informed consent; and (4) a terminal illness with an expected survival of less than 1 year at enrollment, determined by clinical assessment. Pregnancy, lactation, and older age will not be used as exclusion criteria. Both drug-susceptible and drug-resistant TB cases will be included in the study.

Participants will be enrolled from two populations: (1) those initiating or actively receiving anti-TB treatment (treatment-phase group), and (2) individuals with documentation of completed pulmonary TB treatment within the prior 5 years (post-treatment group). The treatment-phase group will serve as the main cohort for evaluating PTLT incidence and longitudinal changes. The post-treatment group will contribute to exploratory analyses.

Although specific quotas for sex or age categories are not established, demographic balance will be assessed throughout recruitment at all study sites. If significant disparities are detected, strategies for enrollment will be modified to support diversity and generalizability.

4. Study procedures

Eligible individuals who provide informed consent will undergo baseline assessment capturing demographics, respiratory symptoms, chest imaging, laboratory findings, comorbidities, and quality of life metrics. Baseline and follow-up data will be systematically collected over a 5-year timeframe following the end of TB treatment.

For individuals who are currently receiving TB treatment (treatment-phase group), the date of TB treatment initiation serves as the baseline. Since the standard duration of TB treatment typically ranges from 6 to 9 months—even in cases of multidrug- or rifampicin-resistant TB in current practice¹²—follow-up assessments are scheduled at 6 and 12 months after baseline to obtain clinical data at or near the completion of therapy. Thereafter, additional follow-up assessments are performed annually for up to 5 years following the end of treatment. The timing of follow-up assessments may be adjusted at the discretion of the attending physician. Furthermore, unscheduled visits initiated by the patient are allowed.

For participants who have completed TB treatment

and are enrolled during the post-treatment period, the baseline is still considered the date of TB treatment initiation. The entire follow-up period, including the interval between treatment initiation and study enrollment, is counted from this baseline, with ongoing follow-up extending up to 5 years after treatment completion. For instance, if a participant is enrolled 1 year after completing TB therapy, follow-up will be maintained for an additional 4 years to achieve a total of 5 years of post-treatment monitoring (Table 1).

5. Study outcomes

The primary outcome is the presence of PTLT during follow-up, defined using standardized, clinically relevant criteria. A participant will be classified as having PTLT if one or more of the following criteria are fulfilled: (1) Impaired pulmonary function (forced expiratory volume in 1 second [FEV₁] or forced vital capacity [FVC] <80% of predicted, or FEV₁/FVC <70%); (2) Radiographic evidence of post-TB sequelae (e.g., fibrosis, bronchiectasis, air trapping, or pleural thickening); (3) Persistent respiratory symptoms, such as chronic cough, sputum production, or dyspnea (modified Medical Research Council [mMRC] scale ≥ 1) persisting longer than 3 months; or (4) Decreased health-related quality of life in respiratory-specific domains, as determined by validated measurement tools.

6. Data collection

At enrollment, detailed baseline information will be systematically collected from all participants. This will comprise demographic variables including age and sex, as well as socioeconomic factors such as marital status, occupation, education level, smoking and alcohol histories, and nationality. In addition, anthropometric data—specifically height, weight, waist, and mid-upper arm circumference—as well as clinical parameters such as blood pressure, pulse rate, and body temperature will be obtained.

Clinical data on comorbidities will be systematically obtained through the Charlson comorbidity index, which covers a standardized list of chronic diseases such as myocardial infarction, heart failure, peripheral vascular disease, cerebrovascular disease, chronic pulmonary disease, diabetes, liver disease, renal impairment, malignancy, and human immunodeficiency virus infection. Details regarding current medication use, with a specific focus on therapies relating to respiratory and metabolic disorders, will be recorded. Respiratory symptoms, such as cough, sputum production, dyspnea (measured using the mMRC scale), chest pain, and constitutional symptoms, will be systematically

Table 1. Timeline of data collection

	Baseline	Month 6	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6
Informed consent	•							
Anthropometric measurements	•	•	•	•	•	•	•	•
Medical history	•	•	•	•	•	•	•	•
Sputum study	•	•	•	•	•	•	•	•
Drug susceptibility test	•							
Chest imaging	•	•	•	•	•	•	•	•
Blood tests	•	•						
Serologic tests	•							
Urinalysis	•							
Electrocardiogram	•							
Spirometry		•	•	•	•	•	•	•
Quality of life questionnaire	•	•	•	•	•	•	•	•

documented. Health-related quality of life will be evaluated using validated Korean versions of the Euro-Qol 5-Dimension 5-Level (EQ-5D-5L)¹³⁻¹⁵ and Patient-Reported Outcome Measurement Information System (PROMIS)¹⁶⁻¹⁸. Each questionnaire has undergone Korean translation and validation for use in the Korean population. Data specific to TB, including history of previous TB or latent TB infection, site of involvement, date of treatment initiation, and treatment regimen, will be obtained.

Radiological assessment will involve chest X-rays and, when available, chest computed tomography (CT) scans, to identify findings such as cavities, bronchiectasis, fibrotic changes, and interstitial abnormalities. Microbiological evaluation will cover specimen type, results of acid-fast bacilli (AFB) smear and culture, nucleic acid amplification tests, and histopathological examination as relevant. Laboratory investigations will include standard biochemistry, hematology, inflammatory markers, glucose and lipid profiles, vitamin D status, serology for human immunodeficiency virus and viral hepatitis, and electrocardiography. Drug susceptibility testing will use both molecular and phenotypic approaches, incorporating Xpert MTB/RIF Ultra (Cepheid, Sunnyvale, CA, USA) or similar platforms, as well as line probe assays for isoniazid and rifampin.

During follow-up visits, key data will be systematically collected at each time point to monitor disease progression and post-TB outcomes. This process will cover updates on smoking history, body weight, comorbidities, medications, as well as respiratory symptom profiles and dyspnea scores. Quality of life assessments will be repeatedly conducted using EQ-5D-5L,

PROMIS, and the St. George's Respiratory Questionnaire^{19,20}. Imaging modalities will be performed annually, with CT scans scheduled at years 1, 2, 4, and 6. Follow-up bacteriologic and laboratory assessments will include routine sputum AFB smear and culture tests and blood panels at 6 months. Pulmonary function tests²¹ will commence post-treatment to evaluate lung volumes and gas exchange capacity, with baseline assessments deferred due to infection control measures during active TB.

This structured and repeated approach to data collection over multiple time points allows for robust determination of PTLT prevalence and the longitudinal evolution of lung function and health-related quality of life. The projected sample size ensures sufficient statistical power to detect clinically significant within-subject changes and to characterize temporal trends and risk predictors throughout the study period.

7. Data management and monitoring

Participant data will be collected by attending investigators and certified clinical research coordinators. All personally identifiable information will be removed from the source documents, and anonymized data will be entered into the web-based electronic case report form, which is managed by an independent external agency (M2community, Seoul, Korea, <https://www.m2community.co.kr/>). Only authorized personnel, including approved attending investigators and clinical research coordinators designated by the Institutional Review Board (IRB) of each site, will have access to the study data. Documents with participants' personal information and signed consent forms will be maintained

securely on-site in locked cabinets within secure offices with restricted access. Data collection practices will be subject to periodic review and oversight by the principal investigator at each site throughout the study duration. Furthermore, regular research meetings, including attending investigators, will be held to monitor study conduct and ensure data quality.

8. Sample size calculation

To establish a nationwide, prospective, multicenter registry to assess the current burden of PTLD in Korea, we calculated the necessary sample size using data from previous systematic reviews and meta-analyses reporting a post-TB respiratory impairment prevalence of 20% to 25%²². Assuming a prevalence of 25%, a 95% confidence interval, and a 5% margin of error, the minimum required sample size was calculated at 288. With an anticipated 10% withdrawal rate, the final target sample size was set at approximately 320 participants²³. This sample size estimation pertains specifically to the treatment-phase cohort, which enables the prospective assessment of PTLD incidence and longitudinal progression.

9. Safety statement

As this is an observational study without any interventions beyond standard clinical care, no direct benefit or harm to participants is anticipated.

10. Drop-out of participants

Participants retain the right to withdraw from the study at any point, after which they will be classified as drop-outs. In the event of participant death during follow-up, the event will be considered as a study outcome rather than a drop-out. All collected data up to the point of withdrawal or death will be included in the final analysis.

11. Statistical analysis

Continuous variables will be reported as means with standard deviation (if normally distributed) or as medians with interquartile range. Categorical variables will be described using frequencies and percentages. Continuous variables will be compared using the Student's t-test (for variables with normal distribution) or the Mann-Whitney U test, while categorical variables will be analyzed using chi-square or Fisher's exact tests, as appropriate. Multivariate logistic regression and Cox proportional hazards models will be utilized to determine the influence of each determinant on study outcomes.

12. Ethics statement

The study protocol and informed consent documents were approved by the IRB of Severance Hospital and by each participating center (2024-3575-001). Written informed consent will be secured from all participants by the responsible investigators before enrollment. The present investigation will adhere to the principles of the Declaration of Helsinki, and all procedures will be conducted following applicable guidelines. This study is registered at ClinicalTrials.gov (NCT06946784, <https://clinicaltrials.gov/ct2/show/NCT06946784>).

Discussion

TB has afflicted humanity for centuries, and similarly, PTLD—previously termed TB-destroyed lung or TB-associated chronic obstructive pulmonary disease (COPD)—has also long been recognized as a persistent sequela of pulmonary TB. Nevertheless, focused research and clinical attention to PTLD have only recently begun to increase. Consequently, there is a lack of clear consensus regarding the optimal timing and methods for identifying individuals with PTLD, as well as uncertainty about appropriate management strategies and recommended follow-up care. Given Korea's rapidly aging population and rising life expectancy attributable to medical advancements, the prevalence and impact of PTLD are projected to increase consistently²⁴. Under these circumstances, the implementation of evidence-based policies is crucial to maintain effective and sustainable TB control initiatives, and prospective cohort studies are indispensable for generating the scientific data necessary to inform these policy decisions²⁵. In light of Korea's distinct TB epidemiological characteristics, the LIFE-TB study aims to provide essential evidence supporting the development of PTLD-specific guidelines tailored for the national healthcare context.

To fulfill this objective, the LIFE-TB study was established as a nationwide, multicenter, prospective cohort investigation focusing on the long-term outcomes of pulmonary TB in Korea. The study will systematically gather comprehensive data, encompassing respiratory symptoms, pulmonary function, chest imaging findings, quality of life metrics, comorbidities, and relevant laboratory results. All collected information will be maintained on a centralized web-based platform, subject to regular monitoring procedures to ensure data integrity and protocol compliance. This meticulous approach facilitates prospective assessment of PTLD progression, healthcare resource utilization, and key risk factors for adverse outcomes, thereby providing a solid basis for

the development of future clinical guidelines and policy recommendations.

Several studies have recently focused on the long-term consequences of TB, underscoring an increasing global awareness of the health burdens following TB. For instance, the TB Sequel study is a multi-country, multicenter cohort conducted in four African nations, designed to clarify the incidence, pathogenesis, and risk factors for both medical and socioeconomic sequelae of pulmonary TB²⁶. This study recruited over 1,600 participants at TB diagnosis and integrates analyses of host immunity, microbiology, and cost-related factors, with a primary outcome of severe lung function impairment assessed at 24 months after completion of therapy. A prospective Chinese study investigating male smokers and non-smokers seeks to determine serum biomarkers and risk factors associated with PTLT, with biomarker and imaging data obtained over a 3-year observation period after treatment concludes²⁷. Another Chinese nationwide cohort concentrates on a specific phenotype, TB-associated COPD, aiming to delineate its clinical features, natural course, and response to therapy over 1 year, with outcomes compared among individuals with and without a prior history of TB²⁸. In South Africa, an implementation study has started to evaluate the practical effectiveness and feasibility of spirometry screening for early detection of PTLT among adolescent and adult survivors of TB, employing a hybrid effectiveness-implementation framework to guide the routine adoption of lung function assessments in clinical care²⁹.

Although these studies yield valuable perspectives on particular domains of post-TB outcomes, the LIFE-TB study is distinguished by its comprehensive inclusion of respiratory, cardiovascular, psychosocial, and functional assessments over a prolonged 5-year follow-up, independent of smoking status or comorbid COPD. Unlike protocols limited to specific diseases or biomarker endpoints, LIFE-TB employs a more inclusive, population-based design that incorporates heterogeneous patient groups, such as older adults, individuals with drug-resistant TB, and patients with substantial comorbid conditions.

Despite its strengths, the LIFE-TB study is subject to several limitations. First, while the study intends to recruit participants from multiple tertiary hospitals across Korea, there remains a risk that the cohort does not fully capture the broader TB survivor population, especially individuals receiving care in primary settings or those who are socially marginalized. Second, although the cohort encompasses a wide range of clinical and quality of life parameters, it does not include biomark-

er-based analyses or mechanistic studies, highlighting the need for future translational research to enhance and extend these findings.

In summary, the LIFE-TB study is a nationwide, prospective cohort established to systematically evaluate the long-term effects of TB on pulmonary function and overall well-being among individuals in Korea. Through serial collection of detailed clinical, functional, and quality of life data, this research seeks to provide evidence that will guide the development of post-TB care interventions tailored to Korea's aging TB survivor population and its changing epidemiological context.

Authors' Contributions

Conceptualization: Chung C, Min J, Jeon D, Kwon YS, Mok J, Kim HW, Kang YA. Methodology: Chung C, Min J, Kang YA. Writing - original draft preparation: Chung C, Min J, Kang YA. Writing - review and editing: Chung C, Min J, Jeon D, Kwon YS, Mok J, Kim HW, Kang YA. Approval of final manuscript: all authors.

Conflicts of Interest

Jinsoo Min is an editor of the journal, but he was not involved in the peer reviewer selection, evaluation, or decision process of this article. No other potential conflicts of interest relevant to this article were reported.

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