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# Studying the interactions of naturally living bacteria in tuberculosis

**Submission date**
29/06/2026

**Recruitment status**
Recruiting

**Registration date**
02/07/2026

**Overall study status**
Ongoing

**Last Edited**
01/07/2026

**Condition category**
Infections and Infestations

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

## Plain English summary of protocol

Background and study aims
Tuberculosis (TB) is an infectious disease that mainly affects the lungs. Although effective treatment is available, people respond differently to treatment. The lungs naturally contain communities of bacteria, known as the lung microbiome, which may influence how TB develops and how people recover. This study aims to understand how the lung microbiome changes before and after TB treatment and whether these changes are linked to treatment response and long-term health outcomes. The study will also investigate a type of tuberculosis bacteria, called differentially culturable mycobacteria, that can survive despite treatment and may contribute to delayed recovery.

Who can participate?
People aged 16 years or older who are being assessed for suspected pulmonary tuberculosis or have confirmed pulmonary tuberculosis and are receiving care through the Leicester TB service

What does the study involve?
The study will collect samples from the lungs during bronchoscopy, together with sputum and swab samples from the mouth, tongue and throat to study the microbiome. Blood samples will also be collected. Participants will undergo a range of clinical and research assessments, including chest imaging, lung function tests, body composition measurements, and questionnaires about their health and quality of life. Muscle biopsy, muscle strength assessments, and physical activity monitoring are optional. Most study visits will be coordinated with routine hospital appointments wherever possible.

What are the possible benefits and risks of participating?
Participants may not receive any direct medical benefit from taking part. However, the information gained may improve understanding of tuberculosis and help develop better ways of predicting and monitoring treatment response in future patients.
Some study procedures may cause temporary discomfort or inconvenience. Bronchoscopy, blood sampling and muscle biopsy (if undertaken) carry small risks, which will be explained fully before participants provide consent. If additional chest X-rays or CT scans are performed solely for

research purposes, participants will be exposed to a small amount of additional radiation. The associated risks will be explained in full before participants provide informed consent. Standard clinical care will not be affected by participation in the study.

Where is the study run from?
The study is coordinated by the NIHR Leicester Biomedical Research Centre, University Hospitals of Leicester NHS Trust, in collaboration with the University of Leicester (UK)

When is the study starting and how long is it expected to run for?
August 2026 to July 2029

Who is funding the study?
Medical Research Council (MRC) (UK)

Who is the main contact?
Dr Pranabashis Haldar, ph62@leicester.ac.uk

# Contact information

### Type(s)
Principal investigator, Scientific, Public

### Contact name
Dr Pranabashis Haldar

### Contact details
NIHR Biomedical Research Centre, Groby Road
Leicester
United Kingdom
LE3 9QP
+44 (0)1162583472
ph62@leicester.ac.uk

# Additional identifiers

### Integrated Research Application System (IRAS)
373739

# Study information

### Scientific Title
Microbiome Interactions in Tuberculosis (MERIT)

### Acronym
MERIT

### Study objectives
Primary objectives:
1. To study microbiome biogeography of the lower respiratory tract in pre- and post-pulmonary TB treatment

2. To characterise differentially culturable tubercule bacilli (DCMTB) sub-populations in treatment-naïve pulmonary TB patients

Secondary objectives:
To study the relationship between microbiome biomarkers and pulmonary TB treatment response characterised by the trajectory of radiological, microbiological, physiological and metabolic responses

## Ethics approval required
Ethics approval required

## Ethics approval(s)
Not yet submitted

## Primary study design
Observational

## Secondary study design
Longitudinal study

## Study type(s)

## Health condition(s) or problem(s) studied
Pulmonary tuberculosis

## Interventions
This study is a prospective, longitudinal observational study, conducted at Glenfield Hospital, University Hospitals of Leicester NHS Trust, Leicester, UK. Participants will be recruited from the outpatient and inpatient tuberculosis services at Glenfield Hospital. Both suspected and confirmed TB patients will be recruited.

Participants with confirmed pulmonary TB will be followed up along with routine clinical appointments – baseline, 2 weeks, 8 weeks, 16 weeks and 24 weeks after starting anti-TB treatment and at the end of treatment. 6 months and 12 months after the end of treatment visits will be optional. Participants will undergo routine clinical tests such as blood tests, CXR, CT, bronchoscopy and sputum collection as well as research tests such as blood tests, bronchoscopy (if not done as a routine clinical test), bioelectrical impedance analysis (BIA), dual energy x-ray absorptiometry (DEXA), EQ-5D-5L questionnaires, spirometry, and sputum collection. Muscle biopsy, muscle function assessments and physical activity monitoring are optional.

Participants who are confirmed not to have tuberculosis following bronchoscopy will continue to undergo the same research procedures as those with confirmed tuberculosis, up to 8 weeks. After that, participants will be discharged from the study and will continue their care through routine clinical services.

Clinical protocols of care, including investigations and therapy decisions, will not be influenced in any way by study enrolment.

## Intervention Type
Other

### Primary outcome(s)
1. Microbial diversity and composition measured using richness, Pilous evenness, Berger-Parker dominance, Shannon and Simpson indices to explore alpha diversity and Jaccard, Bray-Curtis and Unifrac measures to explore beta diversity, at before and after anti tuberculosis treatment (the standard duration of anti-tuberculosis treatment is 6 months; however, treatment may be extended to 9 or 12 months if response to treatment is considered unsatisfactory)

### Key secondary outcome(s)
1. Clinical responses measured using demographics, symptom burden, health-related quality of life (measured using EQ-5D-5L questionnaire), and lung function test with spirometry
2. Microbiological responses measured using smear status, Xpert grade, time to positive culture, molecular and phenotypic drug sensitivity
3. Radiological responses: CXR and CT to determine % lung involvement and evidence of extrapulmonary disease
4. Physiological and metabolic responses measured using physical activity monitoring (PAM), muscle function assessments (MFAs) with handgrip strength and quadriceps strength tests, muscle biopsy, body composition measurements with dual energy x-ray absorptiometry (DEXA) scan and bioelectrical impedance analysis (BIA)

Measured at 2 weeks, 8 weeks, 16 weeks and 24 weeks after the anti-tuberculosis treatment start date and end of treatment. Participation at 6 months and 12 months after the treatment end date is optional.

### Completion date
31/07/2029

## Eligibility

### Key inclusion criteria
1. Provision of informed consent
2. Aged 16 years or older
3. Engagement with the Leicester Clinical TB service with either suspected TB or active TB disease

### Healthy volunteers allowed
No

### Age group
Mixed

### Lower age limit
16 Years

### Upper age limit
100 Years

### Sex
All

### Total final enrolment

0

### Key exclusion criteria
1. Any chronic medical disorder which, in the opinion of the investigator, may either put the subject at risk (because of participating in the study) or may influence the results of the study or the subjects' ability to participate in the study
2. Donation of blood >450 ml within 3 months of study commencement or during the study (other than for study purposes).
3. Pregnancy or lactation
4. Participation in an interventional clinical study in the 3 months prior to of Visit 1 or participation in a study using interventional medicinal products in the previous 6 months
5. Previous chemotherapy for LTBI in the last 5 years
6. Previous treatment for active TB disease in the last 2 years

### Date of first enrolment
03/08/2026

### Date of final enrolment
31/07/2028

## Locations

### Countries of recruitment
United Kingdom

England

### Study participating centre
**University Hospitals of Leicester NHS Trust**
Leicester Royal Infirmary
Infirmary Square
Leicester
England
LE1 5WW

## Sponsor information

### Organisation
University of Leicester

### ROR
https://ror.org/04h699437

## Funder(s)

### Funder type

### Funder Name
Medical Research Council

### Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, Medical Research Committee and Advisory Council, MRC

### Funding Body Type
Government organisation

### Funding Body Subtype
National government

### Location
United Kingdom

## Results and Publications

### Individual participant data (IPD) sharing plan

### IPD sharing plan summary
Not expected to be made available