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Study to assess whether point-of-care lung ultrasound and patient factors are related to tuberculosis severity and disability

Submission date
14/08/2025

Recruitment status
No longer recruiting

Registration date
04/09/2025

Overall study status
Ongoing

Last Edited
26/08/2025

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 remains one of the leading causes of morbidity and mortality globally, with high rates of infection in low- and middle-income countries. Early and accurate assessment of TB severity is crucial for tailoring appropriate treatments and improving long-term patient outcomes, particularly in reducing disability and preventing death. Despite advancements in clinical diagnostics, there is still a need for more accessible, non-invasive tools for TB monitoring. Lung ultrasound, a non-invasive, portable and low-cost imaging technique, has shown promising results in detecting pulmonary abnormalities and evaluating disease severity in various lung diseases, including TB. This study in Peru aims to evaluate whether POCUS lung can detect TB and if it can be used to detect and predict TB disease severity and disability.

Who can participate?
This project will use a case-control design, enrolling participants diagnosed with TB (cases) and healthy community members (controls).
For cases, adults (≥18 years old) diagnosed with TB and who have initiated TB treatment (for no more than 2 weeks) or are about to initiate TB treatment at health facilities, are part of ongoing cohort study (called PREVENIR) and do not have a severe illness or life-threatening condition will be eligible to participate in this study.
For controls, adults (≥18 years old) living in the community who are part of an ongoing cohort study (called PRESIENTE), have not had TB treatment in the last year and do not have a severe illness or life-threatening condition, will be eligible to participate in the study

What does the study involve?
Participants will be assessed at baseline and again after 12 months. At baseline physical examination, a questionnaire on clinical information and disability and data collection from health records will be performed, as well as a point-of-care lung ultrasound and collection of a sputum sample. Additional examinations, such as blood pressure, glucose or HIV tests, will be performed. At the follow-up visit, physical examination, questionnaire on disability, data collection from health records and sputum sample collection will take place, together with verbal autopsy in case of death.

What are the possible benefits and risks of participating?
Potential benefits for participants are:
1. Free use of a simple, safe and non-invasive tool which could identify prior undiagnosed medical problems
2. TB screening in community controls, who in the event that they are positive will be referred for care and treatment initiation
3. In cases, people living with TB, provision of direct drug-susceptibility testing that is currently not routinely provided by the National TB program. In the event that drug resistance is identified, the results will be shared with the participants and the local physicians for management
4. Other quick referrals for identified problems
5. Other quicker results feedback than routine standard of care
Wider community potential benefits are:
1. Contribute to the availability of a tool that was previously not available at the health facilities
2. Opportunity to partake in a potential landmark study that could influence future policy
3. Training of facility radiographers in lung ultrasound and therefore capacitating health facilities
4. Potential better TB treatment monitoring, allowing better clinical management, reducing resistance and transmission within communities and improving progress towards the goal of ending tuberculosis
We do not anticipate any potential risk for participants and ultrasound is a non-invasive tool. There might be, however, potential discomfort derived from exposure of the upper body for obtaining ultrasound images or from collecting sputum samples. HIV testing may cause mild discomfort and learning about HIV status may cause distress.

Where is the study run from?
Asociacion Benéfica PRISMA (Peru)

When is the study starting and how long is it expected to run for?
March 2025 to March 2027

Who is funding the study?
National Institute for Health and Care Research (NIHR) (UK)

Who is the main contact?
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
NIHR156579

Study information

Scientific Title
Formative prospective case–control study on Point-of-Care Lung Ultrasound and clinical–epidemiological factors to evaluate their association with Tuberculosis severity and predict disability (POCUS4TB-Peru)

Acronym
POCUS4TB_Perú

Study objectives
TB is a major global health concern, particularly in areas with limited access to advanced diagnostic tools. Traditional methods, such as chest X-rays, are not always available in these settings. Point-of-care ultrasound (POCUS) is a non-invasive, affordable, and portable alternative. In this study we want to assess whether there is a correlation between POCUS images and the severity of TB disease and disability. This would make POCUS a promising, reliable tool for diagnosing, monitoring, and managing TB, improving patients' outcomes, while also allowing the identification of individuals at higher risk of long-term health consequences, leading to better-targeted interventions.

Ethics approval required
Ethics approval required

Ethics approval(s)

1. submitted 31/03/2025, London School of Hygiene and Tropical Medicine (Keppel Street, London, WC1E 7HT, United Kingdom; +44 (0)20 7636 8636; ethics@lshtm.ac.uk), ref: 32198

2. submitted 08/04/2025, PRISMA ethics comitee (Av. Guardia Civil 1321, Lima, 15036, Peru; +51 (0)(511) 209 0400; prisma@prisma.org.pe), ref: CEO135.25

3. notYetSubmitted, Universidad Peruana Cayetano Heredia (Address not provided, Lima, Zip /postal code not provided, Peru; Telephone number not provided; Email not provided), ref: Reference number not provided

Study design
Prospective case-control study

Primary study design
Observational

Study type(s)
Diagnostic, Quality of life

Health condition(s) or problem(s) studied
Tuberculosis

Interventions
This study will recruit adults living with TB attending health facilities (cases) and adults without TB living in the community (controls).

The cases will be recruited from ongoing cohort (PREVENIR) of consecutive adult patients (≥18 years old) with TB, these will be invited to participate if they have just been diagnosed with TB, and/or have recently started treatment for TB at health facilities for no longer than 2 weeks, and who do not have any serious illness resulting in unstable or life-threatening condition.

The controls will be recruited from an ongoing cohort in the community (PRESIENTE) to identify acute respiratory infections (ARI) and acute gastroenteritis. Adults will be invited to participate if ≥18 years old, if they have not received TB treatment in the last year and if they do not have any serious illness resulting in an unstable or life-threatening condition. Controls will further be divided into two groups: (a) “healthy community controls” who do not have any respiratory symptoms; and (b) “respiratory community controls” who have been identified to have an acute respiratory infection (ARI) episode.

In both cases and controls, after informed consent has been provided, a questionnaire will be carried out, as well as data collection from study records, followed by physical examination (including measurements such as weight, height, blood pressure and glucose and HIV testing). Disability will be assessed using the Disability (EQ-5D-5L). Point-of-care ultrasound (POCUS) will be conducted by trained research staff and a sputum sample will be collected to assess bacteriological load and drug resistance.

Follow-up will be conducted at 12 months after TB treatment initiation for cases and after recruitment for controls. A questionnaire will be performed and data will be collected from health records, to obtain information on updated survival status and TB treatment outcomes in cases. Physical examination, tests and measurements as in the baseline visit will be conducted. In case of death, a verbal autopsy will be performed. Disability and well-being will also be assessed

using EQ-5D-5L and WHO BREF QOL questionnaires. A sputum sample will also be collected from cases.

Intervention Type
Other

Primary outcome(s)
Diagnostic performance of point-of-care ultrasound (POCUS) for detecting tuberculosis is measured in terms of sensitivity, specificity, positive predictive value, and negative predictive value, by comparing the interpretation of ultrasound images by two independent readers to bacteriologically and/or clinically confirmed TB at the baseline visit

Key secondary outcome(s))
1. Disability measured using EQ-5D-5L questionnaire at baseline and at 12 months
2. Quality of life measured using WHO BREF QO questionnaire and calculating quality-adjusted life years (QALYs) at baseline and at 12 months
3. Mortality measured through questionnaire to household members at 12 months
4. Cause of death evaluated through verbal autopsy conducted to household members of those deceased
5. Lung abnormalities suggestive of TB, measured using POCUS images interpreted by two independent readers in cases and controls at baseline and at 12 months
6. Disease severity measured using mycobacterial load in sputum samples at baseline and at 12 months

Completion date
31/03/2027

Eligibility

Key inclusion criteria
Inclusion criteria for cases:
1. Current participant of the PREVENIR study
2. Aged ≥18 years old
3. Receiving or will receive treatment for TB at the selected health centre

Inclusion criteria for controls:
1. Current participant in the PRESIENTE study
2. Aged ≥18 years old

Participant type(s)
Healthy volunteer, Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
100 years

Sex
All

Key exclusion criteria
Exclusion criteria for cases:
1. Started treatment >2 weeks ago for the current TB episode
2. Serious illness resulting in an unstable condition or life-threatening participation in the study

Exclusion criteria for controls:
1. Received TB treatment <1 year ago.
2. Serious illness resulting in an unstable condition or life-threatening participation in the study

Date of first enrolment
15/09/2025

Date of final enrolment
31/03/2026

Locations

Countries of recruitment
Peru

Study participating centre
Asociación benéfica PRISMA
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Sponsor information

Organisation
London School of Hygiene & Tropical Medicine

ROR
https://ror.org/00a0jsq62

Organisation
Prisma

ROR
https://ror.org/011y8cj77

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a publicly available repository (yet to be confirmed)

IPD sharing plan summary
Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Study website	Study website	11/11/2025	11/11/2025	No	Yes