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Using point-of-care lung ultrasound to explore how TB severity affects people's socio-economic status

Submission date
14/08/2025

Recruitment status
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 (TB) remains a major global health challenge, especially in low-resource settings where timely diagnosis and treatment are often limited. People with lower socioeconomic status tend to face more barriers to early TB diagnosis, which can lead to more severe illness, worse health outcomes, and continued transmission in their communities. In turn, severe TB can deepen financial hardship through high treatment costs and lost income, creating a cycle in which poverty and TB reinforce each other.
The World Health Organization (WHO) recommends active screening for people at higher risk of TB. Conventional screening methods, such as chest X-rays, can be effective but are often unavailable in remote areas due to the need for specialized equipment and trained staff. Point-of-care ultrasound (POCUS) offers a portable and promising alternative for screening and monitoring TB, potentially enabling earlier diagnosis and improving patients' socioeconomic circumstances.
This study aims to explore the relationship between TB severity and its socioeconomic impacts, as well as to evaluate the use of POCUS for early TB diagnosis and disease severity assessment, and its potential role in improving patients' economic and social well-being.

Who can participate?
Adults recently diagnosed with TB who are receiving care at a health facility (cases), and adults randomly selected from the community (controls)

What does the study involve?
Baseline visit: After obtaining informed consent, all participants will complete an interview to assess socioeconomic status, followed by a physical examination (including measurements such as weight and height) and a point-of-care ultrasound (POCUS). Relevant clinical data will also be extracted from participants' medical records.
Follow-up visits: Only participants with TB (cases) will be followed up at 2 and 6 months after starting treatment. At each follow-up, they will undergo repeat socioeconomic interviews, physical examinations and measurements, POCUS, and medical record review

What are the possible benefits and risks for participants?
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 the 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 HIV testing, which may cause mild discomfort too 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 from?
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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Study information

Scientific Title
Point-Of-Care Ultrasound for Tuberculosis Formative Prospective case-control study with nested cohort in Bolivia: characterising associations between disease severity and the socioeconomic consequences of TB

Acronym
POCUS4TB_Bolivia

Study objectives
Tuberculosis (TB) remains a global health concern, particularly in low-resource settings where access to diagnostics and timely treatment is limited. Lower socioeconomic status is associated with reduced access to timely tuberculosis diagnosis, contributing to increased disease severity and poorer outcomes, as well as ongoing transmission within communities. In turn, greater disease severity can exacerbate socioeconomic hardship through catastrophic health-related costs, creating a reinforcing cycle between poverty and TB.

The WHO recommends actively screening populations at higher risk of TB. While conventional screening tools such as chest X-rays are useful, they are often inaccessible in remote areas due to the need for specialized equipment and personnel. Point-of-Care Ultrasound (POCUS) has emerged as a promising, portable alternative for screening and monitoring TB, which could lead to easier access and early diagnosis of TB and potentially improve the socioeconomic conditions of patients.

In this study we aim to better understand associations between TB disease severity and the socioeconomic consequences of TB disease. As well as assessing the use of POCUS for early diagnosis of TB and for assessing TB disease severity, and its role in improving patients´ socio-economic status.

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: 32195

2. submitted 08/04/2025, PRISMA ethics committee (Av. Guardia Civil 1321, Lima, 15036, Peru; +51 (0)(511) 209 0400; prisma@prisma.org.pe), ref: CEO136.25

3. submitted 17/04/2025, Universidad Catolica Boliviana (Av. 14 de Septiembre Nº 4807, La Paz, 00591, Bolivia; +591 (2) 278222; coonalinv.cba@ucb.edu.bo), ref: N/A

Study design
2:1 case-control study (cases are participants diagnosed with TB versus community controls) with a nested prospective cohort of participants diagnosed with TB

Primary study design
Observational

Study type(s)
Other, Screening

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

Interventions
This is a 2:1 case-control study, in which adults recently diagnosed with TB attending a health care facility will be invited to participate (cases), as well as adults randomly selected from the community (controls).

Baseline Visit:
After obtaining informed consent, participants will undergo interviews to assess socioeconomic status, and a physical examination, including measurements such as weight and height, will be conducted together with a point-of-care ultrasound (POCUS). Clinical data will be collected from participants´ records.

Follow-up Visits:
Follow-up visits will be conducted only for participants diagnosed with TB (cases) at 2 and 6 months post-treatment, with repeat interviews to assess socioeconomic status, physical examination and measures, data collection from medical records and POCUS.

The study will focus on using POCUS to better understand TB disease severity and its socioeconomic impact. POCUS images will also be used to train an AI model that could improve TB screening and triage in the future.

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 interpretation of ultrasound images by two independent readers to bacteriologically and/or clinically confirmed TB at baseline visit

Key secondary outcome(s))
1. Socioeconomic status measured using TB-household income at baseline
2. TB-related costs measured using a questionnaire designed for this purpose at baseline
3. Quality of life measured using the WHO BREF QOL questionnaire at baseline
4. Disease severity measured using symptom duration, body mass index, sputum mycobacterial concentration and POCUS images interpreted by two independent readers in participants with TB (cases) at baseline and 2 and 6 months

Completion date
31/03/2027

Eligibility

Key inclusion criteria
For participants diagnosed with TB (cases):
1. Aged ≥18 years old
2. Receiving or will receive treatment for pulmonary TB at the selected health centre

For community controls:
1. Aged ≥18 years old
2. Resides in the selected community

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

For participants diagnosed with TB (cases):
1. Started treatment >2 weeks for the current TB episode
2. Refusing to provide informed consent/assent to participate in the study

For community controls:
1. Received TB treatment <1 year ago
2. Refusing to provide informed consent/assent to participate in the study
3. Serious illness resulting in unstable condition or life-threatening participation in the study

Date of first enrolment
15/09/2025

Date of final enrolment
01/10/2026

Locations

Countries of recruitment
Bolivia

Peru

Study participating centre
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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