

Risk factors of negative outcomes for pleural tuberculosis

Submission date 09/04/2026	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 10/04/2026	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 10/04/2026	Condition category Infections and Infestations	<input type="checkbox"/> Individual participant data
		<input checked="" type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Tuberculous empyema is a serious condition where infected fluid collects around the lungs. It can be difficult to treat and may require surgery. This study aims to better understand which factors affect recovery, complications, and relapse.

Who can participate?

Patients diagnosed with tuberculous empyema who were treated in specialized tuberculosis centers between 2003 and 2023 and have complete medical records.

What does the study involve?

This is a retrospective study. Researchers review existing medical records to collect information about patient characteristics, type of treatment (medical, minimally invasive surgery, or open surgery), and outcomes. No new treatments or procedures are given.

What are the possible benefits and risks of participating?

There are no direct benefits or risks, as no interventions are performed. The study may help improve future treatment strategies.

Where is the study run from?

Three tuberculosis centers in Russia.

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

The study analyzes data from 2003 to 2023 and is expected to be completed in 2026.

Who is funding the study?

Investigator initiated and funded.

Who is the main contact?

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Contact information

Type(s)

Scientific, Principal investigator, Public

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Additional identifiers**Study information****Scientific Title**

The outcome determinants in tuberculous empyema

Acronym

TBEMP1

Study objectives

To evaluate the correlation between treatment strategy, disease stage, and microbiological characteristics to determine outcomes in patients with tuberculous empyema

Ethics approval required

Ethics approval required

Ethics approval(s)

approved 02/04/2026, Local Ethics Committee of Sechenov University (Trubetskaya 8, Moscow, 119048, Russian Federation; +7(495)6229706; iec@staff.sechenov.ru), ref: 08-26

Primary study design

Observational

Secondary study design

Epidemiological study

Study type(s)**Health condition(s) or problem(s) studied**

Patients with diagnosed tuberculosis empyema

Interventions

This study is designed as a multicenter retrospective observational cohort study evaluating clinical outcomes in patients with tuberculous empyema treated between 2003 and 2023 across

three tuberculosis centers. Medical records of patients with suspected tuberculous empyema are reviewed for eligibility.

Participants are included if a confirmed diagnosis of tuberculous empyema is established and sufficient data on treatment strategy and clinical outcomes are available. Exclusion criteria include alternative pleural disease etiology, incomplete follow-up data, performance of lung resection procedures in addition to empyema management, and presence of human immunodeficiency virus infection.

Interventions are not assigned but reflect routine clinical practice and include conservative management (pleural drainage and antitubercular therapy), video-assisted thoracoscopic surgery, or open surgical procedures.

Data collected include demographic, clinical, and microbiological variables. Outcomes assessed include relapse, residual radiological changes, and duration of pleural exudation. Multivariable statistical models are applied to evaluate independent predictors of outcomes.

Intervention Type

Procedure/Surgery

Primary outcome(s)

1. Relapse measured using the occurrence of empyema requiring further treatment according to medical documentation at 3 years at one time point
2. Residual radiological changes measured using the presence of radiological signs of pulmonary fibrosis or fibrothorax in medical documentation at 3 years at one time point
3. Duration of pleural exudation in days measured using medical documentation at 3 years at one time point
4. Mortality (%) measured using medical documentation at 30 days at one time point

Key secondary outcome(s)

Completion date

01/01/2026

Eligibility

Key inclusion criteria

1. Diagnosed tuberculosis empyema
2. Sufficient documentation of clinical presentation, treatment strategy, and outcomes

Healthy volunteers allowed

No

Age group

Mixed

Lower age limit

18 years

Upper age limit

100 years

Sex

All

Total final enrolment

1052

Key exclusion criteria

1. Patients with different pathology
2. Absent follow-up
3. Lung resections alongside surgical or conservative management of empyema
4. Patients with HIV

Date of first enrolment

01/09/2023

Date of final enrolment

31/12/2023

Locations**Countries of recruitment**

Russian Federation

Sponsor information**Organisation**

Sechenov University

ROR

<https://ror.org/02yqqv993>

Funder(s)**Funder type****Funder Name**

Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not expected to be made available