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Risk factors of negative outcomes for pleural tuberculosis

Submission date	Recruitment status	[_] Prospectively registered
09/04/2026	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
10/04/2026	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
10/04/2026	Infections and Infestations	[X] 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?
Prof Boris Giller, gillerbd@gmail.com, giller-thorax@mail.ru

Contact information

Type(s)
Scientific, Principal investigator, Public

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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 ocurrence 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