

# Comparing surgical treatment outcomes in patients with different lung diseases and breathing tube repair types

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<b>Registration date</b> 20/09/2021	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 20/09/2021	<b>Condition category</b> Surgery	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

A pneumonectomy is a type of surgery to remove one of your lungs because of cancer, trauma, or some other condition.

After surgery there is a high risk of complications that may lead to death.

This trial aims to investigate which type of bronchi suture (the method used to close the end of the breathing tube in the removed lung) would better prevent complications after pneumonectomy in patients with different diseases.

### Who can participate?

All patients who have had a pneumonectomy from 1959 to 2021 in six different Russian hospitals.

### What does the study involve?

This is an observational study, which means that participants receive treatment as usual, depending on their condition. Patients receive primary drug treatment in accordance with the recommendations of the Russian Federation, and then they are offered surgery if their doctor think it is needed. Participants could receive medical treatment after surgery if needed.

### What are the possible benefits and risks of participating?

None

### Where is the study run from?

Federal State Autonomous Educational Institution of Higher Education I.M. Sechenov First Moscow State Medical University of the Ministry of Health of the Russian Federation (Sechenov University)

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

August 2021 to September 2021

Who is funding the study?  
Investigator initiated and funded

Who is the main contact?  
Giller Dmitrii Borisovich, giller-thorax@mail.ru

## Contact information

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Scientific

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## Additional identifiers

**Clinical Trials Information System (CTIS)**  
Nil known

**ClinicalTrials.gov (NCT)**  
Nil known

**Protocol serial number**  
U1111-1269-2424

# Study information

## Scientific Title

Broncho-Pleural Complications after Pneumonectomy depending on the disease and the bronchial suture type. Retrospective observational study.

## Acronym

BPCaP

## Study objectives

1. The manual no stump bronchial suture modified by D.B.Giller reduces the bronchopleural fistula risk in oncological, tuberculosis and nonspecific chronic inflammatory lung diseases patients
2. The original trachea-bronchial anastomosis and circular carina resection reduce the anastomosis failure risk.
3. The main bronchi suture modified by B.M.Giller reduces bronchopleural complications risk after pneumonectomy in patients with lung gangrene.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Approved 01/09/2021, I.M. Sechenov First Moscow State Medical University (Sechenov University) Local Ethics Committee (119991, Moscow, 8 Trubetskaya str., Russia; +7(495)622-97-06; iec@staff.sechenov.ru), ref: 15-21

## Study design

Retrospective observational study

## Primary study design

Observational

## Study type(s)

Treatment

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

Pneumonectomy for pulmonary cancer, tuberculosis or nonspecific chronic inflammatory lung diseases.

## Interventions

Patients who underwent pneumonectomy due to tuberculosis, oncology, or nonspecific chronic inflammatory disease are included in this trial. They have undergone treatment according to their disease and treatment standards of the period of hospitalization.

Some patients, especially those with bilateral lesions, have undergone multi-stage surgical treatment. All patients signed a consent form before each intervention.

Patients underwent the following tests:

- Blood test
- Mantoux test
- Diaskin test

- Spirometry
- Blood gases test
- CT scan
- Fibrobronchoscopy
- PET CT
- MRI of the brain
- Ultrasound of the organs of the ruddy cavity
- Microbiological examination of sputum, surgical material with the additional use of accelerated diagnostic methods DR MBT (BACTEC, molecular genetic methods: real-time PCR - Xpert MTB / RIF biochips and PCR-TB; culture method);
- Morphological, histological and cytological examination of biopsy material
- Methods of statistical data processing.

## **Intervention Type**

Procedure/Surgery

## **Primary outcome(s)**

Measured retrospectively using patient records:

1. Bronchopleural fistula development
2. 30-day postoperative mortality rate
3. Postoperative long term bronchopleural complications
4. Postoperative mortality due to bronchopleural complications

## **Key secondary outcome(s)**

Measured retrospectively using patient records:

1. Surgery efficacy in patients with tuberculosis measured using
  - 1.1. Sputum culture conversion rate after surgery and one, three and five years after surgery
  - 1.2. Presence of cavities in pulmonary tissue (CV+/CV-) determined with CT scan/digital X-ray on discharge from the hospital, one, three and five years post-surgery.
2. Surgery efficacy in oncology patients measured using
  - 2.1. Clear resections edges
  - 2.2. R0 resection
  - 2.3. 5-year survival rate
3. Surgery efficacy in patients with nonspecific chronic inflammatory lung diseases measured using absence of inflammatory process according to microbiological, roentgenological and clinical analysis after surgery and one, three and five years after surgery.
4. Five-year survival rate

## **Completion date**

01/09/2021

## **Eligibility**

### **Key inclusion criteria**

All patients who have had a pneumonectomy from 1959 to 2021 at the following institutions:

1. State Budgetary Healthcare Institution "Chelyabinsk Regional Clinical Anti-Tuberculosis Dispensary" 38, Vorovskogo str., Chelyabinsk, Russian Federation, 454092. From 1959 to 2004
2. Central TB Research Institute, 2, Yauzskaya alley, Moscow, Russian Federation, 107564 From 2004-2011
3. Sechenov University Phthisiopulmonology Clinical Hospital, 4, Dostoevskogo str., Moscow, Russian Federation, 127473. From 2011 to 2017

4. Ingush Republican TB Dispensary, 1, Bolnichnaya str., Plievo Village, Nazranovsky District, Republic of Ingushetia, Russian Federation, 386124. From 2018 to 2021
5. Regional Clinical Tuberculosis Dispensary, 22, Volskaya str., Saratov, Russian Federation, 410056. From 2018 to 2021
6. JSC «MEDICINE» (CLINIC OF ACADEMICIAN ROYTBERG), 10, 2nd Tverskoy-Yamskoy Pereulok, Moscow, Russian Federation, 125047. From 2018 to 2021

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

All

**Sex**

All

**Total final enrolment**

2001

**Key exclusion criteria**

1. Patients admitted before 14/11/1959 and after 01/09/2021
2. Patients who passed lung resections in volume less than pneumonectomy

**Date of first enrolment**

14/11/1959

**Date of final enrolment**

01/09/2021

**Locations****Countries of recruitment**

Russian Federation

**Study participating centre**

**State Budgetary Healthcare Institution "Chelyabinsk Regional Clinical Anti-Tuberculosis Dispensary"**

38, Vorovskogo str.

Chelyabinsk

Russian Federation

454092

**Study participating centre**

**Central TB Research Institute**

2, Yauzskaya alley  
Moscow  
Russian Federation  
107564

**Study participating centre****Sechenov University Phthisiopulmonology Clinical Hospital**

4, Dostoevskogo str.  
Moscow  
Russian Federation  
127473

**Study participating centre****Ingush Republican TB Dispensary**

1, Bolnichnaya str., Plievo Village, Nazranovsky District, Republic of Ingushetia  
Plievo Village  
Russian Federation  
386124

**Study participating centre****Saratov Regional Clinical Tuberculosis Dispensary**

22, Volskaya str.  
Saratov  
Russian Federation  
410056

**Study participating centre****JSC «MEDICINE» (CLINIC OF ACADEMICIAN ROYTBERG)**

10, 2nd Tverskoy-Yamskoy Pereulok  
Moscow  
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125047

**Sponsor information****Organisation**

Sechenov University

**ROR**

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

## **Funder(s)**

**Funder type**

Other

**Funder Name**

Investigator initiated and funded

## **Results and Publications**

**Individual participant data (IPD) sharing plan**

All data generated or analysed during this study will be included in the subsequent results publication.

**IPD sharing plan summary**

Other