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

Submission date	Recruitment status	[ ] Prospectively registered
16/09/2021	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
20/09/2021	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
20/09/2021	Surgery	[ ] 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

Type(s)
Scientific

Contact name
Prof Dmitry Giller

ORCID ID
http://orcid.org/0000-0003-1946-5193

Contact details
19, Detskaya str.
Moscow
Russian Federation
107258
+7 9168681291
giller-thorax@mail.ru

Type(s)
Public

Contact name
Prof Dmitry Giller

Contact details
19, Detskaya str.
Moscow
Russian Federation
107258
+7 9168681291
giller-thorax@mail.ru

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers

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

Secondary study design
Case-control study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not applicable (retrospective study)

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 measure
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

Secondary outcome measures
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 chronical 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

Overall study start date
30/08/2021

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

Age group
All

Sex
Both

Target number of participants
2001

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
Moscov
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
Russian Federation
125047

Sponsor information

Organisation
Sechenov University

Sponsor details
8-2 Trubetskaya str.
Moscow
Russian Federation
119991
+7 (495) 622-95-86
id@1msmu.ru

Sponsor type
University/education

Website
https://sechenov.ru/eng/

ROR
https://ror.org/02yqqv993

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
26/07/2022

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