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Surgical treatment outcomes in patients passed VATS thoracoplasty for pulmonary tuberculosis

Submission date
01/08/2019

Recruitment status
No longer recruiting

Registration date
05/08/2019

Overall study status
Completed

Last Edited
23/11/2020

Condition category
Respiratory

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Tuberculosis (TB) is a bacterial infection that commonly affects the lungs. There are antibiotics that can treat TB, but some strains of the bacteria are resistant to one or more of these antibiotics and the infection can become hard to treat using medicines. It is also possible to treat drug-resistant TB with surgery, by removing infected parts of the lung or collapsing the lung to close cavities. The aim of this study is to follow-up patients with TB who passed surgery for lung cavities collapsing to investigate how surgical treatment affects their TB infection status.

Who can participate?
All patients at a Moscow Hospital with spread TB who had no indications for lung resection between 1999 and 2017.

What does the study involve?
This is an observational study, which means that participants received treatment as usual depending on their condition. Patients received initial drug treatment according to Russian Federation guidelines and then were offered surgery if their doctor thought it was appropriate. Participants could receive drug treatment after surgery as appropriate.

What are the possible benefits and risks of participating?
There were no additional risk for participants enrolled in the study, because their treatment was performed according to guidelines. Participants could benefit from free examinations and additional follow-up and treatment.

Where is the study run from?
I.M. Sechenov First Moscow State Medical University (Russian Federation)

When is the study starting and how long is it expected to run for?
January 1999 to December 2017

Who is funding the study?
The investigator is funding the study.

Who is the main contact?
Professor Dmitry Giller, giller-thorax@mail.ru

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
U1111-1237-3349

Study information

Scientific Title
VATS Treating Thoracoplasty in Destructive Pulmonary Tuberculosis Treatment

Acronym
ThorTB

Study objectives
VATS thoracoplasty application has the same efficacy rate as a standard one but without the typical side effects (chest deformation, muscle atrophy, shoulder girdle dysfunction, etc.).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 17/07/2019, I.M. Sechenov First Moscow State Medical University (Sechenov University) Local Ethics Committee 119991 (8 Trubetskaya str. Building 1, Moscow, Russia; +7 495 622-97-06), ref: 10-19

Study design
Observational retrospective study

Primary study design
Observational

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Pulmonary tuberculosis

Interventions
Patients with determined destructive pulmonary tuberculosis resistance were enrolled in study.

Before surgery was considered, they were treated with antitubercular chemotherapy using one of the standard chemotherapy regimens in the Russian Federation (Guidelines for improving the diagnosis and treatment of respiratory tuberculosis (approved by order of the Ministry of Health of the Russian Federation dated December 29, 2014 No. 951) depending on the degree of drug resistance and patient examination.

Indications for thoracoplasty were single/multiple cavity(ies) in the upper-posterior segments of the upper lobe and/or S6 of the one/both lungs combined with massive seeding that does not allow for a lung resection to be performed. In addition, we often perform this technique to correct the hemithorax volume after lung resections for prevention of pulmonary tissue hyperextension and TB reactivation. Other important data in favor of surgical treatment are MDR or XDR mycobacteria, absence of positive dynamics despite adequate regimen, and timing of chemotherapy and pulmonary hemorrhage.

The surgery technique involves an incision of 4–8 cm on the decostation side along the paravertebral line in the projection of the II–IV rib necks. Together with the scapula, the dissected muscles are retracted from the external surface of the ribs, that creates cavity above decostation plane. With thoracoscopy application, we perform upper ribs resection to create collapse on affected pulmonary parenchyma.

Between 1999 and 2017, we performed 925 VATS thoracoplasties. In 208 patients it was employed as a treating procedure. All patients signed consent before every intervention. Follow-up was performed regularly for up to 5 years, with observation duration of 6 years.

All groups received treatment in the same hospital and received the following tests:
1. Blood test
2. Mantoux test
3. Diaskin test
4. Spirometry
5. Blood gases
6. CT scan

7. Fibrobronchoscopy;
8. Microbiological examination of sputum, an operational material with the additional use of accelerated diagnostic methods of DR MBT (BACTEC, molecular genetic methods: real-time PCR - Xpert MTB / RIF and PCR-TB biochips; cultural method);
9. Morphological study of gross section
10. Methods of statistical data processing.

Intervention Type
Procedure/Surgery

Primary outcome(s)
1. Presence of cavities in pulmonary tissue (CV+/CV-) determined with CT scan/digital X-ray on discharge from the hospital.
2. Presence of M tuberculosis assessed using AFB smear test of sputum (AFB+/AFB-) using sputum fluorescent microscopy and culture method on discharge from the hospital.

Key secondary outcome(s))
1. Presence of cavities in pulmonary tissue (CV+/CV-) determined with CT scan/digital X-ray every year for 5 years (1st, 2nd, 3rd, 4th, 5th year) after discharge.
2. Presence of M tuberculosis assessed using AFB smear test of sputum (AFB+/AFB-) using sputum fluorescent microscopy and culture method every year for 5 years (1st, 2nd, 3rd, 4th, 5th year) after discharge.
3. TB relapse assessed by clinical follow-up for up to 5 years (1st, 2nd, 3rd, 4th, 5th year) after discharge.

Completion date
23/12/2017

Eligibility

Key inclusion criteria
1. Diagnosis of pulmonary tuberculosis.
2. Admitted to our clinic between 1999 and 2017.
3. Indications for thoracoplasty.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
All

Sex
All

Total final enrolment
208

Key exclusion criteria
N/A

Date of first enrolment
01/09/2017

Date of final enrolment
23/12/2017

Locations

Countries of recruitment
Russian Federation

Study participating centre
I.M. Sechenov First Moscow State Medical University (Sechenov University)
8 Trubetskaya str.
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Sponsor information

Organisation
I.M. Sechenov First Moscow State Medical University (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

The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary

Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/03/2020	23/11/2020	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes