Surgical treatment outcomes in patients passed VATS thoracoplasty for pulmonary tuberculosis

Submission date	Recruitment status No longer recruiting	Prospectively registered		
01/08/2019		Protocol		
Registration date 05/08/2019	Overall study status Completed	Statistical analysis plan		
		[X] Results		
Last Edited 23/11/2020	Condition category Respiratory	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 Prof Dmitry Giller

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Additional identifiers

EudraCT/CTIS number Nil known

IRAS number

ClinicalTrials.gov number Nil known

Secondary identifying numbers 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

Secondary study design Cohort study

Study setting(s) Hospital

Study type(s) Treatment

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

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 measure

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.

Secondary outcome measures

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.

Overall study start date

01/01/1999

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

Age group All

Sex Both

Target number of participants 208

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. Moscow Russian Federation 119048

Sponsor information

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

Sponsor details 8 Trubetskaya str. Moscow Russian Federation 119048 +7 (495) 622-95-86 id@1msmu.ru

Sponsor type University/education

Website https://www.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

A publication titled "VATS Treating Thoracoplasty in Destructive Pulmonary Tuberculosis Treatment " is planned to be submitted to a journal by 01/08/2019.

2018 results presented at the 26th European Conference on General Thoracic Surgery in http://www.ests2018.com/static/upload/ow76/events/ev195/Site/files /ESTS18_Publication_BoA_v3-2205.pdf Book of Abstracts (see abstract P-74, page 289)

Intention to publish date

01/02/2020

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