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Comparing surgical treatment outcomes in patients with different levels of drug-resistant tuberculosis

Submission date
01/07/2019

Registration date
02/07/2019

Last Edited
02/07/2019

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

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, whether they were treated with surgery or not, so investigate how surgical treatment affects their TB infection status, level of disability and survival.

Who can participate?
All patients at a Moscow Hospital who were diagnosed with drug-resistant TB between 2011 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?
October 2011 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

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

Contact details
I.M. Sechenov First Moscow State Medical University (Sechenov University)
8 Trubetskaya str.
Moscow
Russian Federation
119048
+79168681291
giller-thorax@mail.ru

Additional identifiers

Protocol serial number
U1111-1236-2168

Study information

Scientific Title
Pulmonary tuberculosis surgical treatment in patients with multiple and extensive drug-resistant mycobacterial infection

Acronym
PTS MEDR

Study objectives
Radical and semi-radical surgical treatment application can increase treatment efficacy of patients with destructive pulmonary tuberculosis with multiple and extensive drug-resistant Mycobacterium tuberculosis infection.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Approved 06/03/2013, 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: 03-13

Primary study design
Observational

Study design
Observational retrospective study

Study type(s)
Treatment

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

Interventions
Patients with determined drug resistance were enrolled in study and divided into five groups depending on drug resistance: extensively drug-resistant (XDR), multiple drug-restistant (MDR), poly-drug-resistant (PolyDR), monodrug-resistant (MonoDR) and drug-sensitive (DS).
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) https://www.garant.ru/products/ipo/prime/doc/70749840/) depending on the degree of drug resistance and patient examination. Before surgery patients had on average 3-6 months of chemotherapy.
Then surgery was performed. Some patients, especially with bilateral lesions had multistage surgical treatment. Overall 2172 surgeries was performed in 1259 patients. Surgeries performed were: thoracoplasty, segmentectomy, combined polysegmental resections, lobectomy, bilobectomy, lobectomy plus segmentectomy, pneumonectomy, pleuropneumonectomy, transsternal main bronchus occlusion. All patients signed consent before every intervention.
Follow-up was performed regularly up to 5 years, with observation duration of 6 years.
For a more objective assessment of the study results , each of the above groups were divided into three subgroups, depending on the radical surgery degree:
- Radical (no TB alterations in pulmonary parenchyma and intrathoracic lymphadenopathy [ITLN] verified with computerise tomography [CT])
- Semi-radical (remaining foci or tuberculomas without destruction in operated/contralateral lung; cases with remained cavern under thoracoplasty were also included, because tendency for cavity closureis usually observed in terms up to 6 months.)
- Palliative (cases with bilateral cavitary TB, when surgery was applied just on one side due to patient’s rejection of treatment or low cardiorespiratory reserves; elimination of life-threatening conditions without destructions removal)

All groups received treatment in the same hospital and received the following tests:
- Blood test
- Mantoux test
- Diaskin test
- Spirometry
- Blood gases
- CT scan
- Fibrobronchoscopy;

- 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);
- Morphological study of gross section
- 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 up to 5 years (1st, 2nd, 3rd, 4th, 5th year) after discharge.
4. Degree of disability assessed by checking patients' documentation and anamnesis (patentient's account of medical history) during follow-up up to 5 years (1st, 2nd, 3rd, 4th, 5th year) after discharge.
5. Survival assessed by follow-up up to 5 years (1st, 2nd, 3rd, 4th, 5th year) after discharge.

Completion date
23/12/2017

Eligibility

Key inclusion criteria
Every patient with a diagnosis of drug-resistant M tuberculosis admitted in our clinic between 2011 and 2017 was included in this study.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
All

Sex
All

Key exclusion criteria

Patients with unknown drug resistance admitted in our clinic between 2011 and 2017

Date of first enrolment
16/10/2011

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)

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

Data sharing statement to be made available at a later date