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Surgical treatment outcomes in patients with different pulmonary diseases caused by Mycobacteria

Submission date
14/11/2021

Recruitment status
No longer recruiting

Registration date
17/11/2021

Overall study status
Completed

Last Edited
09/01/2024

Condition category
Surgery

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

Plain English summary of protocol

Background and study aims
Mycobacteria are a group of different bacteria that include those that cause tuberculosis (TB) among other illnesses. Nontuberculous mycobacterial pulmonary disease is a disease of the lungs caused by mycobacteria that do not cause tuberculosis. Nontuberculous mycobacterial pulmonary disease is an important public health issue because there is an increase in cases and medications are becoming less effective. This trial's aim is to find out how useful and safe surgery is for patients with nontuberculous mycobacterial pulmonary disease, a combination of nontuberculous mycobacterium lung disease and pulmonary tuberculosis compared with cavitary pulmonary tuberculosis.

Who can participate?
All patients who had lung operations because of nontuberculous mycobacterial pulmonary disease, a combination of nontuberculous mycobacterium lung disease, and pulmonary tuberculosis from 2011 to 2017, and cavitary pulmonary tuberculosis from 2016 to 2017 in Sechenov University Phthisiopulmonology Clinical Hospital.

What does the study involve?
In this study, patients will receive treatment as usual and are observed for the outcomes of this treatment. The treatment they received depends on their condition and drug resistance results. Patients received primary drug treatment in the way that the Russian Phthisiopulmonogy society recommends. They were received then offered surgery if their doctor thought it was needed. Participants also received medical treatment after surgery if required.

What are the possible benefits and risks of participating?
Participants included in the study are not at additional risk because they were treated as recommended. Their benefits are free examination and added observation and treatment.

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 (Russian Federation)

When is the study starting and how long is it expected to run for?
From October 2019 to December 2021

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
U1111-1271-6052

Study information

Scientific Title
Surgical treatment outcomes in patients with a diagnosis of nontuberculous mycobacterial pulmonary disease, a combination of nontuberculous mycobacterium pulmonary disease and pulmonary tuberculosis, or cavitary pulmonary tuberculosis: a retrospective observational study

Acronym
STOMDs

Study objectives
1. Surgical treatment with a background of properly conducted chemotherapy allows for constant disease remission in patients with nontuberculous mycobacterial pulmonary disease, a combination of nontuberculous mycobacterium pulmonary disease and pulmonary tuberculosis, or cavitary pulmonary tuberculosis
2. Surgical treatment of nontuberculous mycobacterial pulmonary disease, a combination of nontuberculous mycobacterium pulmonary disease and pulmonary tuberculosis, or cavitary pulmonary tuberculosis is sufficiently safe for patients
3. Surgical treatment could be required in case of a rare combination of nontuberculous mycobacterium pulmonary disease and pulmonary tuberculosis
4. Video-assisted thoracoscopic surgery (VATS) technologies and the combination of lung resections with thoracoplasty can improve treatment outcomes

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 07/04/2021, I.M. Sechenov First Moscow State Medical University (Sechenov University) Local Ethics Committee (8 Trubetskaya str., Moscow, 119991; +8(495)622-97-06; iec@staff.sechenov.ru)

Study design
Retrospective observational study

Primary study design
Observational

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Surgical outcomes of patients with nontuberculous mycobacterial pulmonary disease, a combination of nontuberculous mycobacterium pulmonary disease and pulmonary tuberculosis, or cavitary pulmonary tuberculosis

Interventions
This study will investigate the outcomes of treatment in a cohort of patients admitted to hospital between January 2011 and December 2017, who underwent resectional lung surgery for nontuberculous mycobacterial pulmonary disease, a combination of nontuberculous mycobacterium lung disease and pulmonary tuberculosis, or cavitary pulmonary tuberculosis. Participants were treated according to their disease and treatment guidelines during the period of hospitalization. Some patients, especially those with bilateral lesions, have undergone multi-stage surgical treatment. All patients signed a consent form prior to medical intervention.

Intervention Type
Procedure/Surgery

Primary outcome(s)
1. Sputum culture conversion after surgery measured using microscopic examination (AFB smear); samples, which were cultured on Lowenstein–Jensen (L-J) medium and molecular diagnostic testing after surgery
2. 30 -day postoperative mortality rate measured using patient records at 30 days post-surgery
3. Intra- and postoperative complications measured using patient follow-up at 1, 3, and 5 years post-surgery
4. Postoperative mortality due to pulmonary disease and any other possible causes measured using patient follow-up at 1, 3, and 5 years post-surgery

Key secondary outcome(s))
1. Sputum culture conversion rate measured using microscopic examination (AFB smear); samples, which were cultured on Lowenstein–Jensen (L-J) medium and molecular diagnostic testing after surgery and at 1, 3, and 5 years post-surgery
2. Presence of cavities in pulmonary tissue (CV+/CV-) measured using CT scan/digital X-ray on discharge from hospital at 1, 3, and 5 years post-surgery
3. Five-year survival rate measured using patient follow-up at 5 years post-surgery

Completion date
30/12/2021

Eligibility

Key inclusion criteria
Surgery performed at Sechenov University Phthisiopulmonology Clinical Hospital to treat one of the following:
1. Nontuberculous mycobacterial pulmonary disease between 2011 and 2021
2. A combination of nontuberculous mycobacterium pulmonary disease and pulmonary tuberculosis between 2011 and 2021
3. Cavitary pulmonary tuberculosis from 2016 to 2017

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
All

Sex
All

Total final enrolment
83

Key exclusion criteria
1. Admitted before January 2011 and after December 2017
2. Received lung resections and/or do not have the nontuberculous mycobacterial pulmonary disease, a combination of nontuberculous mycobacterium lung disease and pulmonary tuberculosis, or cavitary pulmonary tuberculosis

Date of first enrolment
11/06/2011

Date of final enrolment
26/10/2017

Locations

Countries of recruitment
Russian Federation

Study participating centre
Sechenov University Phthisiopulmonology Clinical Hospital
4, Dostoevskogo str.
Moscow
Russian Federation
127473

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
The datasets generated and analysed during the current study will be published as a supplement to the subsequent results publication.

IPD sharing plan summary
Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	Nontuberculous mycobacterial pulmonary disease and NTMPD and pulmonary tuberculosis results (NTMPD) and	07/04/2022	11/04/2022	Yes	No
Other publications	additional analysis to compare clinical and radiographic signs of NTMPD, XDR pTB, or a combination of NTMPD and pTB,	09/06/2023	09/01/2024	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes