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Comparison of two methods of lymph node removal in patients suffering from lung cancer

Submission date 09/11/2017	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 20/11/2017	**Overall study status** Ongoing	
Last Edited 24/01/2025	**Condition category** Cancer	

Plain English summary of protocol

Background and study aims
Lung cancer is the number 1 killer among all malignancies in both sexes. The most effective way to treat it is complete surgical resection (removal of part of the lung), which is possible in less advanced cases. Together with the diseased part of the lung, also lymph nodes are removed, as they often are cancer deposits. The standard systematic lymph node dissection (SLND) removes nodes but this only removes nodes from one side of the chest. Unfortunately, cancer deposits can develop also in the contralateral (opposite) side of the chest. This study is aimed at assessment of bilateral removal of the lymph nodes during lung cancer surgery.

Who can participate?
Adults aged 18 with non-small cell lung cancer.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group have their lung resection done with the standard procedure. Those in the second group receive the standard procedure as well as an additional lymph node dissection in the other side of their chest through a neck incision. Participants are followed for operative time, blood loss, number of lymph nodes removed and any other complication during the surgery. Participants are followed up after the surgery for their pain and survival.

What are the possible benefits and risks of participating?
The potential benefit is more complete resection achieved with bilateral removal of lymph nodes, resulting in better chance for cure. There is a possible increased risk of adverse effects as the procedure is more invasive.

Where is the study run from?
This study is being run by Jagiellonian University and takes place in hospitals in Poland, China, Germany, Austria, and Turkey.

When is the study starting and how long is it expected to run for?
January 2017 to December 2025

Who is funding the study?
1. Jagiellonian University in Krakow (Poland)
2. Sun Yat-sen University Cancer Center (China)
3. Catholic Hospital Koblenz (Germany)
4. Otto Wagner Hospital, Vienna (Austria)
5. ELK Berlin Chest Hospital, Berlin (Germany)
6. Istanbul University, Cerrahpasa Medical Faculty (Turkey)
7. Thoraxzentrum Ruhrgebiet (Germany)
8. University of Giessen (Germany)

Who is the main contact?
Professor Jaroslaw Kuzdzal

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
1072.6120.91.2017

Study information

Scientific Title
Comparison of unilateral and Bilateral Mediastinal Lymph node dissection in patients with non-small cell lung cancer

Acronym
BML-2

Study objectives

In patients operated on for non-small cell lung cancer, bilateral mediastinal lymph node dissection is associated with improved survival as compared with standard systematic lymph node dissection.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 30/06/2017, Bioethical Committee of the Jagiellonian University (ul. Podwale 3/5, Cracow, 31-118, Poland; +48123704386; kbet@cm-uj.krakow-pl), ref: 1072.6120.91.2017

Study design
Prospective multicentre study

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
See study outputs table

Health condition(s) or problem(s) studied
Non-small cell lung cancer

Interventions
Prospective multicentre study with 1:1 randomisation using computer-generated random numbers. The intervention group includes patients undergoes bilateral mediastinal lymph node dissection (BML), and the control group includes participants who undergo standard systematic lymph node dissection (SLND).

Randomisation in the ratio 1:1 using computer-based random digit generator. All participants receive anatomical lung resection with SLND is performed according to the ESTS guidelines. VATS and thoracotomy approaches are acceptable. In the BML group, additional contralateral lymph node dissection is performed during the same anaesthesia, via separate neck incision (using either the VAMLA technique,10 or modified TEMLA technique15).

The following intraoperative parameters are recorded: operative time, blood loss, number of lymph nodes removed from each nodal station, any complications.

The following postoperative parameters are recorded: volume of chest tube output, time of chest drainage, time of air leak, pain intensity measured using the visual analogue scale (VAS), any complications, tumour relapse and survival recorded at least every three months in the first three years, and at least every six months in the 4th and 5th year after surgery.

Patients with stage pII or pIII (according to the final pathological report) are referred for adjuvant platinum-based chemotherapy.

Intervention Type
Procedure/Surgery

Primary outcome measure
1. Overall and cancer-specific 5-year survival rate is measured using the CRF data at 5-year survival is by definition measured 5 years after initiation of the treatment
2. DFS is measured using the CRF data at the time of closing the study 5 year after treatment of the last patient included

Secondary outcome measures
1. Operative time is measured using case report forms at the end of the procedure
2. Blood loss is measured using the scale of the suction device container at the end of the procedure
3. Pain intensity measured using VAS every 4 hours at the days 0, 1, 2, 3, 4, and 5
4. Complications is measured using the CRF data that include records of 45 categories of adverse effects at day of discharge
5. Length of hospital stay is measured using hospital records at the day of discharge
6. Number of removed lymph nodes in each station is counted by the pathologist during the final pathological examination of the surgical specimen

Overall study start date
15/01/2017

Completion date
31/12/2025

Eligibility

Key inclusion criteria
1. Age ≥18 years
2. Proven or suspected NSCLC
3. Clinical stage I, II or minimal N2 IIIA, assessed on the basis of CT, PET-CT (except of T1a-b), bronchoscopy and EBUS/EUS (except of T1a-b)
4. General fitness enabling appropriate pulmonary resection (according to the ERS/ESTS guidelines) (both genders are included, this onfo has been given elsewhere in your on-line form)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
306

Total final enrolment
307

Key exclusion criteria
1. History of other malignance (except on non-melanoma skin cancer)
2. Final pathological report of tumour other than NSCLC
3. Final pathological report of carcinoid or salivary gland-type tumour
4. Intraoperative finding of M1 disease

Date of first enrolment
30/11/2017

Date of final enrolment
24/05/2022

Locations

Countries of recruitment
Austria

China

Germany

Poland

Türkiye

Study participating centre
John Paul II Hospital
Department of Thoracic Surgery
Jagiellonian University
Krakow
Poland
31-202

Study participating centre
Sun Yat-sen University Cancer Center
Department of Thoracic Surgery
Guangzhou
China
510060

Study participating centre
Istanbul University
Department of Thoracic Surgery
Cerrahpasa Medical Faculty
Istanbul
Türkiye
34734

Sponsor information

Organisation
Jagiellonian University

Sponsor details
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/03bqmcz70

Funder(s)

Funder type
University/education

Funder Name
Uniwersytet Jagielloński w Krakowie

Alternative Name(s)
Universitas Jagellonica Cracoviensis, Jagiellonian University in Krakow, UJ

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
Poland

Funder Name
Sun Yat-sen University Cancer Center

Funder Name
Catholic Hospital, Koblenz, Germany

Funder Name
Otto Wagner Hospital, Vienna, Austria

Funder Name
ELK Berlin Chest Hospital, Berlin, Germany

Funder Name
Istanbul University, Cerrahpasa Medical Faculty, Istanbul, Turkey

Funder Name
Thoraxzentrum Ruhrgebiet (Germany)

Funder Name
University of Giessen

Results and Publications

Publication and dissemination plan
The study is planned to be presented during oncological and thoracic surgical conferences, and publication of its results is planned in high-impact peer-reviewed journals.

Intention to publish date
31/03/2020

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are not expected to be made available due to the legal regulations of patients' data protection. The data will be stored at the John Paul II Hospital, Krakow, Poland.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet		13/11/2017	02/04/2019	No	Yes
Results article		02/07/2024	04/07/2024	Yes	No
Results article		08/01/2025	10/01/2025	Yes	No