

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

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| <b>Submission date</b><br>09/11/2017   | <b>Recruitment status</b><br>No longer recruiting | <input checked="" type="checkbox"/> Prospectively registered<br><input type="checkbox"/> Protocol |
| <b>Registration date</b><br>20/11/2017 | <b>Overall study status</b><br>Completed          | <input type="checkbox"/> Statistical analysis plan<br><input checked="" type="checkbox"/> Results |
| <b>Last Edited</b><br>24/01/2025       | <b>Condition category</b><br>Cancer               | <input type="checkbox"/> Individual participant data  |

## 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**

Prof Jaroslaw Kuzdzal

**Contact details**

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## Additional identifiers

**Protocol serial number**

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

### **Primary study design**

Interventional

### **Study design**

Prospective multicentre study

### **Study type(s)**

Treatment

### **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,<sup>10</sup> or modified TEMLA technique<sup>15</sup>).

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(s)**

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

### **Key secondary outcome(s)**

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

**Completion date**

31/12/2025

## Eligibility

**Key inclusion criteria**

1. Age  $\geq 18$  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 info has been given elsewhere in your on-line form)

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

All

**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

**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

**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? |
|---|---------|--------------|------------|----------------|-----------------|
| <a href="#">Results article</a>               |         | 02/07/2024   | 04/07/2024 | Yes            | No              |
| <a href="#">Results article</a>               |         | 08/01/2025   | 10/01/2025 | Yes            | No              |
| <a href="#">Participant information sheet</a> |         | 13/11/2017   | 02/04/2019 | No             | Yes             |