

# Does providing low-medium flow of oxygen to the non-ventilated lung during one-lung ventilation prevent lung injury?

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<b>Registration date</b> 22/10/2019	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 17/10/2019	<b>Condition category</b> Respiratory	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

When people have surgery on their lungs, for example to remove lung cancer, sometimes it is necessary to stop the affected lung from inflating with air or to collapse it so that the surgeon can see and access the lung or other nearby parts. This is called one-lung ventilation (OLV) and the entry of air into the lungs is controlled using a ventilator (breathing machine). The lung that is collapsed can become injured because of lack of oxygen and this can cause serious illness. This study aims to investigate whether providing a lower than normal flow of oxygen to the non-inflated lung during the surgery can protect it from injury.

### Who can participate?

Patients aged 18-64 years with lung cancer who were scheduled to undergo surgery requiring OLV.

### What does the study involve?

Participants were randomly divided into one of two groups. In one group, the patients were provided with continued low-medium flow oxygen to the non-inflated lung. The other group had the standard procedure, in which the non-inflated lung was not provided with oxygen. Both groups had the surgery they needed as usual once one lung had been collapsed.

### What are the possible benefits and risks of participating?

All of the participants had a reduction to the anesthesia cost.

### Where is the study run from?

Zhongnan Hospital of Wuhan University (China)

### When is the study starting and how long is it expected to run for?

July 2016 to May 2017

### Who is funding the study?

The researchers funded the trial themselves.

Who is the main contact?  
Tang-Jing Wu, 1154033602@qq.com.

## 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**  
N/A

## Study information

**Scientific Title**  
Effect of continuous administration of low-medium flow oxygen to the non-ventilated lung during one-lung ventilation surgery on blood gas analysis and oxidative stress response in lung tissue of tumor patients: A randomized controlled trial

**Study objectives**  
Continuous administration of low-medium flow oxygen for non-ventilated lung (NVL) during one-lung ventilation (OLV) provides adequate oxygen supply in the NVL and avoid the interference of the operation view. We wish to investigate the effect of continuous administration of low-medium flow oxygen for NVL during OLV on oxidative stress in lung tissue of patient, and to seek a new protective strategy for acute lung injury (ALI).

**Ethics approval required**  
Old ethics approval format

## **Ethics approval(s)**

Approved 02/09/2019, The Medical Ethics Committee of Zhongnan Hospital of Wuhan University (169 Donghu Road, Wuchang District, Wuhan, Hubei, China; +86 027-67812787; znyyll@126.com), ref: 2016020

## **Study design**

Interventional randomized single-centre study

## **Primary study design**

Interventional

## **Study type(s)**

Prevention

## **Health condition(s) or problem(s) studied**

Prevention of acute lung injury in patients undergoing video-assisted thoracoscopic surgery for lung tumor requiring one-lung ventilation

## **Interventions**

Each of the patients who enrolled in the study was randomly divided by the anesthetist into one of two groups by random number table method: experimental group (Group O, continued low-medium flow oxygen in NVL), control group (Group C).

In the experimental group (Group O), one catheter was placed for 2-3cm after the bifurcation of the trachea in the non-ventilated side lung of the patient and continued to be given oxygen at a low medium flow rate of 1-4 l/min. In the control group (Group C), no special treatment was given to the patient after the one-lung ventilation. The surgeon took a biopsy from the tumor in the non-ventilated lung. The total duration of the intervention in experimental group is from the start to the end of one-lung ventilation. The follow-up is end at the time when patients were discharged to the post-anesthesia care unit (PACU) or intensive care unit (ICU). The same surgeons who were blinded to the lung collapse technique performed all surgical procedures. All of the data were recorded by another anesthesiologist who did not know which lung collapse technique had been used.

## **Intervention Type**

Procedure/Surgery

## **Primary outcome(s)**

1. Superoxide dismutase (SOD) level (as a marker of oxidative stress) in lung tumor tissue biopsy from the non-ventilated lung assessed by chemical colorimetry
2. Malondialdehyde (MDA) level (as a marker of oxidative stress) in lung tumor tissue biopsy from the non-ventilated lung assessed by by chemical colorimetry
3. Heme oxygenase-1 (HO-1) expression (as a marker of the body's response to vascular inflammation) in lung tumor tissue biopsy from the non-ventilated lung detected by Western blot

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

Blood gas analysis of radial artery and internal jugular vein collected at induction of anesthesia (T1), 30 min after start of OLV (T2), 1 h after start of OLV (T3) and 2 h after start of OLV (T4)

## **Completion date**

03/05/2017

## Eligibility

### Key inclusion criteria

1. Physical status I or II according to the American Society of Anesthesiologists
2. Age 18-64 years
3. Scheduled to undergo video-assisted thoracoscopic surgery requiring one-lung ventilation (OLV) for the treatment of lung tumor

### Participant type(s)

Patient

### Healthy volunteers allowed

No

### Age group

Adult

### Lower age limit

18 years

### Upper age limit

64 years

### Sex

All

### Total final enrolment

60

### Key exclusion criteria

1. Surgery for more than 4 h
2. Need to stop single lung ventilation during surgery to restore dual lung ventilation to maintain oxygen saturation >90%
3. Patients with immune disease, upper respiratory tract infection, adrenal dysfunction, recent radiotherapy or chemotherapy, pleural effusion, asthma or oral hormonal therapy within 3 months prior to surgery
4. Preoperative pulmonary function tests measured values lower than the minimum required value of various lung resection preoperative pulmonary function test (FEV1 <70% of predicted value)

### Date of first enrolment

02/01/2017

### Date of final enrolment

17/03/2017

## Locations

## Countries of recruitment

China

## Study participating centre

Zhongnan Hospital of Wuhan University

Donghu Road 169

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## Sponsor information

### Organisation

Zhongnan Hospital of Wuhan University

### ROR

<https://ror.org/01v5mqw79>

## Funder(s)

### Funder type

Hospital/treatment centre

### Funder Name

Zhongnan Hospital of Wuhan University

## Results and Publications

### Individual participant data (IPD) sharing plan

The datasets generated during the current study are not publicly available because the authors do not wish to share their data, because the patients who participated in this study did not agree to share their individual data.

### IPD sharing plan summary

Not expected to be made available