

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

Submission date	Recruitment status	<input type="checkbox"/> Prospectively registered
13/10/2019	No longer recruiting	<input type="checkbox"/> Protocol
Registration date	Overall study status	<input type="checkbox"/> Statistical analysis plan
22/10/2019	Completed	<input type="checkbox"/> Results
Last Edited	Condition category	<input type="checkbox"/> Individual participant data
17/10/2019	Respiratory	<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

Contact name

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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; znyll@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 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

Wuhan

China

430000

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes