ISRCTN92523174 https://doi.org/10.1186/ISRCTN92523174

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

Submission date
13/10/2019

Recruitment status
No longer recruiting

Registration date
22/10/2019

Overall study status
Completed

Last Edited
17/10/2019

Condition category
Respiratory

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

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet.

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 biospy 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 measure

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

Secondary outcome measures
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)

Overall study start date
01/07/2016

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

Age group
Adult

Lower age limit
18 Years

Upper age limit
64 Years

Sex
Both

Target number of participants
60

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

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Sponsor type
Hospital/treatment centre

Website
https://znhospital.cn/

ROR
https://ror.org/01v5mqw79

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Zhongnan Hospital of Wuhan University

Results and Publications

Publication and dissemination plan
The results are intended to be published in BMC Anesthesiology by May 2020.

Intention to publish date
01/05/2020

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