ISRCTN12631125 https://doi.org/10.1186/ISRCTN12631125

Effects of tracheotomy high-flow oxygen therapy on respiratory physiology

Submission date	**Recruitment status**	[X] Prospectively registered
24/09/2019	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
10/10/2019	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
14/02/2020	Respiratory	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims

A high-flow system is a kind of device with stable oxygen delivery performance. In clinical practice, high-flow oxygen therapy (HFOT) is widely used in the treatment of hypoxemia (low level of oxygen in the blood) caused by various reasons. A number of studies have shown that compared with standard oxygen therapy, patients with HFOT have better comfort, and the breathing rate and blood oxygenation also have a significant improvement. The beneficial effects of HFOT can be explained by its good tolerance and some physiological characteristics, which include the accurate inhaled oxygen concentration (FiO2), a certain level of positive end-expiratory pressure (PEEP) effect and continuous scour of dead cavities to reduce the CO2 levels of end-expiratory and arteries, it can also reduce the work of breathing. During nasal high-flow oxygen therapy, many studies have shown that the end-tidal lung volume can increase due to the certain level of PEEP effect, but recent studies have pointed out that in patients with brain injury who used the tracheotomy high-flow oxygen therapy (THFO), there is no PEEP effect, and on the contrary, end-tidal lung volume (non-gravity lung) decreased with the increase of flow. This may be related to the work of the patient's expiratory muscles caused by the increased resistance of the expiratory phase. Therefore, this study will further explore whether the changes of the end-tidal lung volume is related to the work of the diaphragm and some expiratory muscles during tracheotomy high-flow oxygen therapy (THFO).

Who can participate?

Patients aged 18 to 70 years old with mild to moderate respiratory distress syndrome and/or hypoxemia

What does the study involve?

Patients will be given oxygen by a conventional tracheotomy mask and tracheotomy high-flow oxygen therapy (THFO). The oxygen flow in the THFO group will be set at 30L/min, 45L/min and 60L/min, each of which lasts for 30 minutes respectively, and during the different oxygen supply modes the changes of end-tidal lung volume will be measured by electrical impedance tomography (ETI), the diaphragm and the related expiratory muscles (mainly including the transversus abdominis muscle) will be measured in the expiratory phase by ultrasound to assess the muscle work. The researchers will also pay close attention to the patient's vital signs, oxygenation and gas exchange at the same time.

What are the possible benefits and risks of participating?
High-flow oxygen therapy can provide stable inhaled oxygen concentration (FiO2) and reduce end-tidal and arterial CO2 levels, thus effectively improving patients' ventilation and oxygenation, and reducing the deterioration of the disease. Some studies have found that tracheotomy high-flow oxygen therapy can increase the successful rate of patients’ detachment from the ventilator, and at present, few reports indicate that oxygen supply by conventional tracheotomy mask and tracheotomy high-flow oxygen treatment are unacceptable, so the hazard risk is known and relatively low.

Where is the study run from?
Sir Run Run Shaw Hospital affiliated to the medical college of ZheJiang University (China)

When is the study starting and how long is it expected to run for?
September 2019 to June 2021

Who is funding the study?
ZheJiang Province Education Department (China)

Who is the main contact?
Jie Ding
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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
Y201636066

Study information

Scientific Title
The relationship between the changes of the end-tidal lung volume and the work of the diaphragmatic muscle and the related respiratory muscles during tracheotomy high-flow oxygen therapy

Study objectives
The end-tidal lung volume (non-gravity lung) changes with the increase of oxygen flow, and the changes may be related to the work of diaphragm and the related expiratory muscles.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 25/11/2016, Ethics committee of Sir Run Run Shaw Hospital affiliated to the medical college of ZheJiang University (310016; Tel: +86 (0)571 86006811), No 20161125-1

Study design
Prospective randomized cross-over study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Patients aged 18 to 70 years old who were successfully detached from the ventilator after tracheotomy in the emergency care unit of Sir Run Run Shaw Hospital

Interventions
Patients were kept in semi-recumbent position (the bed is tilted 30-45 degrees high), and the EIT belt is used to wrap the fifth or sixth intercostal space of the patient's chest, marking the upper and lower edges of the strap to attach to the EIT. Carbon dioxide at the end of expiratory period (PECO2) was monitored by tracheal incision.
A calm environment is ensured around the patients throughout the study. Each patient undergoes four study phases in a computer-generated random order, with each phase lasting 30 min:
1. Conventional tracheotomy mask oxygen therapy, keeping the SpO2 of patients above 95%
2. THFO with gas flow at 30 l/min, keeping the SpO2 of patients above 95%
3. THFO with gas flow at 45 l/min, keeping the SpO2 of patients above 95%
4. THFO with gas flow at 60 l/min, keeping the SpO2 of patients above 95%

Ultrasound will be used to detect the changes of thickness of the diaphragmatic muscle and the related respiratory muscle at various stages, and the end-tidal lung volume will also be measured by electrical impedance tomography (ETI). Then record patients' breathing rate, heart rate, blood pressure, PECO2 and the changes of arterial blood gas at the same time. During the study, other care operations that can affect EIT, such as turning over, position replacement, etc. were all stopped.

Intervention Type
Device

Phase
Not Applicable

Primary outcome(s)
Measured at the completion of each treatment with different oxygen supply modes at 30 minutes:
1. End-tidal lung volume measured using electrical impedance tomography (ETI)
2. Thickness of diaphragmatic muscle and the related respiratory muscle measured by ultrasound

Key secondary outcome(s))
Measured at the completion of each treatment with different oxygen supply modes at 30 minutes:
1. Respiratory rate, heart rate, blood pressure measured using patient monitor (Philips; mode: M8005A)
2. PECO2 measured by the end-of-breath carbon dioxide monitor (mode: M19042000)
3. Arterial blood gas measured by the Automatic blood gas, electrolyte and biochemical analyzer (mode: M18790600)

Completion date
01/06/2021

Eligibility

Key inclusion criteria
1. Aged 18 to 70 years old
2. Patients who successfully detached from the ventilator for 24 years
3. Patients with mild to moderate respiratory distress syndrome and/or hypoxemia
4. Stable vital signs

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Hemodynamic instability (hypotension with mean arterial pressure of <60 mmHg despite volume loads or vasoactive drugs

2. Evidence of pneumothorax on chest X-ray or computed tomography scan
3. Respiratory failure explained by cardiac failure or fluid overload
4. Severe chronic obstructive pulmonary disease
5. Contraindication to electrical impedance tomography (EIT) (e.g. patients with implantable defibrillator, ETI belt positioning with wound dressing or chest drainage tube, etc)

Date of first enrolment
17/10/2019

Date of final enrolment
31/05/2021

Locations

Countries of recruitment
China

Study participating centre
Sir Run Run Shaw Hospital affiliated to medical college of ZheJiang University
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Sponsor information

Organisation
Sir Run Run Shaw Hospital affiliated to medical college of ZheJiang University

ROR
https://ror.org/00ka6rp58

Funder(s)

Funder type
Government

Funder Name
Zhejiang Province Education Department

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be available upon request from Jie Ding (2233702918@qq.com) after article publication. Individual participant data that underlie the results reported in this article, after deidentification (including the changes of end-tidal lung volume and the thickness of diaphragm and the transversus abdominis muscle during different oxygen supply modes of each patient , besides, patient's vital signs, oxygenation and gas exchange will also be provided at the same time) will be shared. The data will be available beginning 9 months and ending 36 months following article publication. Anyone with any purpose who wishes to access the data is OK. The statistical analysis plan will also be available after article publication with the data. Consent from participants was obtained and data is anonymous.

IPD sharing plan summary

Available on request

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