Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 Sep 2026

Investigating the Effect of High-Flow Oxygen Administration on the Weaning Outcomes of Patients from Mechanical Ventilation After Coronary Artery Bypass Graft Surgery

Protocol summary

Study aim

Determining the Effect of High-Flow Oxygen on Weaning Outcomes from Ventilator in Patients After Coronary Artery Bypass Grafting.

Design

Control and intervention groups is conducted on 80 patients undergoing coronary artery bypass graft surgery. Patients were included in the study using a convenience sampling method and then divided into two groups using a simple randomization method.

Settings and conduct

Patients undergoing CABG admitted to the cardiac surgery ICU were included based on inclusion criteria and randomized to control or intervention groups. Ventilator weaning readiness was then assessed using the Burns Wean Assessment Program, and patients scoring above 17 were weaned. The intervention group will receive high-flow oxygen for 12 hours, while the control group receives oxygen via nasal cannula. Outcomes will be measured and compared between groups immediately pre-extubation, and at 6 and 12 hours post-extubation.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: 1.Age ≥18 years old, 2.Mechanical ventilation for a minimum of 12 hours and a maximum of 48 hours 3.No significant bleeding occurred post-surgery (defined as bleeding from the chest tube exceeding 200 ml every hour in the first three hours post-operation). Exclusion Criteria: 1.Severe pneumonia and acute respiratory failure during the study, 2.Persistent ventricular tachycardia requiring therapeutic intervention, 3.Unplanned extubation by the patient 4.Need for tracheostomy placement

Intervention groups

The intervention group will receive high-flow oxygen, while the control group will receive oxygen via nasal cannula.

Main outcome variables

reintubation, arterial blood gas analysis (ABG), ratio of arterial oxygen pressure to inspiratory oxygen fraction, heart rate, mean arterial pressure, systolic blood pressure, diastolic blood pressure, ICU long sta, hospital long stay, mortality

General information

Reason for update

A more accurate translation of the title has been provided. The inclusion and exclusion criteria were changed and revised before the study commenced. The mortality variable was removed from the study's exclusion criteria due to being measured as a secondary outcome. The order of primary and secondary outcomes was revised based on the timing of their measurements. A more accurate translation of the method of randomization has been provided. The method of measurement and description of the variables were edited.

Acronym

IRCT registration information

IRCT registration number: **IRCT20240104060613N1**
Registration date: **2024-02-02, 1402/11/13**
Registration timing: **registered_while_recruiting**

Last update: **2025-03-31, 1404/01/11**
Update count: **1**

Registration date

2024-02-02, 1402/11/13

Registrant information

Name

Abdolrab Dorazehi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 54 3722 6364

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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2024-01-16, 1402/10/26
Expected recruitment end date
2024-12-21, 1403/10/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigating the Effect of High-Flow Oxygen Administration on the Weaning Outcomes of Patients from Mechanical Ventilation After Coronary Artery Bypass Graft Surgery

Public title
Investigating the Effect of High-Flow Oxygen Administration on the Weaning Outcomes of Patients from Mechanical Ventilation After Coronary Artery Bypass Graft Surgery
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Age ≥18 years old Mechanical ventilation for a minimum of 12 hours and a maximum of 48 hours No significant bleeding occurred post-surgery (defined as bleeding from the chest tube exceeding 200 ml every hour in the first three hours post-operation).
Exclusion criteria:
Severe pneumonia and acute respiratory failure during the study Persistent ventricular tachycardia requiring therapeutic intervention Unplanned extubation by the patient Need for tracheostomy placement
Age
From **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **80**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients undergoing mechanical ventilation who met the inclusion criteria were selected using a convenience sampling method and then assigned to two intervention and control groups using a simple randomization method using blue and red colored cards. A total of 80 cards (40 blue cards and 40 red cards) will be prepared in an envelope. The blue cards will be designated for the intervention group, while the red cards will be designated for the control group. Upon the admission of each patient to the intensive care unit, one card will be drawn from the envelope. If a blue card is drawn, the patient will be assigned to the intervention group; if a red card is drawn, the patient will be assigned to the control group. This process will continue until the eightieth card is drawn from the envelope
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Zahedan University of Medical Sciences
Street address
Sistan and Baluchestan Province, Zahedan, Emam Hosain Blvd Integrating the campus of the University of Medical Sciences
City
Zahedan
Province
Sistan-va-Balouchestan
Postal code
9816743463
Approval date
2023-12-24, 1402/10/03
Ethics committee reference number
IR.ZAUMS.REC.1402.388

Health conditions studied

1

Description of health condition studied
Coronary Artery Disease
ICD-10 code
I25.1
ICD-10 code description
Atherosclerotic heart disease of native coronary artery

Primary outcomes

1

Description
Reintubation rate

Timepoint
Forty-eight hours after weaning patients from the ventilator.
Method of measurement
Extubation intolerance leading to respiratory failure and reintubation within 48 hours of weaning.

2

Description
Arterial blood carbon dioxide pressure (PaCO2)
Timepoint
Measurements will be recorded immediately before extubation, and then 6 and 12 hours post-extubation.
Method of measurement
It will be measured through arterial blood gas analysis.

3

Description
Arterial oxygen pressure (PaO2)
Timepoint
Measurements will be recorded immediately before extubation, and then 6 and 12 hours post-extubation.
Method of measurement
It will be measured through arterial blood gas analysis.

4

Description
Arterial blood bicarbonate (HCO3)
Timepoint
Measurements will be recorded immediately before extubation, and then 6 and 12 hours post-extubation.
Method of measurement
It will be measured through arterial blood gas analysis.

5

Description
Arterial oxygen saturation percentage (SPO2)
Timepoint
Measurements will be recorded immediately before extubation, and then 6 and 12 hours post-extubation.
Method of measurement
It is measured through pulse oximeter and arterial blood gas analysis.

6

Description
PaO2/FiO2 ratio
Timepoint
Measurements will be recorded immediately before extubation, and then 6 and 12 hours post-extubation.
Method of measurement
It is calculated by dividing the arterial blood oxygen pressure measured by arterial blood gas analysis by the percentage fractional inspired oxygen (PaO2/FiO2).

7

Description
Heart Rate (HR)
Timepoint
Measurements will be recorded immediately before extubation, and then 6 and 12 hours post-extubation.
Method of measurement
Heart rate is measured via bedside monitoring.

8

Description
Mean arterial pressure (MAP)
Timepoint
Measurements will be recorded immediately before extubation, and then 6 and 12 hours post-extubation.
Method of measurement
Mean arterial pressure (MAP) is measured via patient bedside monitoring.

9

Description
Systolic blood pressure (SBP)
Timepoint
Measurements will be recorded immediately before extubation, and then 6 and 12 hours post-extubation.
Method of measurement
Systolic blood pressure is measured via patient bedside monitoring.

10

Description
Diastolic blood pressure (DBP)
Timepoint
Measurements will be recorded immediately before extubation, and then 6 and 12 hours post-extubation.
Method of measurement
Diastolic blood pressure is measured via patient bedside monitoring.

Secondary outcomes

1

Description
ICU long stay (ILS)
Timepoint
The duration of stay in the intensive care unit (ICU) for open-heart surgery patients is calculated from the day of admission to the day of discharge.
Method of measurement
The number of days admitted to the intensive care unit of patients after coronary artery bypass graft surgery is calculated and recorded from the day of admission to the open heart intensive care unit until discharge from this unit.

2

Description
Hospital long stay (HLS)
Timepoint
From the day of coronary artery bypass surgery until the

day of discharge from the hospital

Method of measurement

The number of days after coronary artery bypass graft surgery will be calculated and recorded from the day of admission to the intensive care unit until the day of discharge from the hospital.

3

Description

Mortality

Timepoint

The mortality rate of patients from the time of admission to discharge from the hospital will be recorded in two groups of intervention and control.

Method of measurement

The mortality rate of patients will be recorded until they are discharged from the hospital.

Intervention groups

1

Description

Intervention Group: In the intervention group, after extubation, high-flow oxygen therapy will be administered using a high-flow oxygen delivery device through a nasal cannula for up to 12 hours. Select an appropriately sized nasal cannula to prevent nasal discomfort. Patients' nostrils are lubricated with petroleum jelly to reduce the risk of epistaxis and dry mucous membranes. The initial oxygen flow rate will be set at 10 liters per minute, and if patients are comfortable, the flow rate will be increased by 5 liters per minute. The temperature of the delivered oxygen will be set at 37 degrees Celsius, and if the patient experiences discomfort, the oxygen temperature will be reduced by one degree down to a minimum of 35 degrees Celsius.The prescribed oxygen flow will be adjusted based on the patients' blood oxygen saturation levels, decreasing or increasing by 5 liters per minute to maintain arterial oxygen saturation levels measured by a pulse oximeter above 90 percent. After 12 hours, high-flow oxygen therapy will be stopped, and if patients still require oxygen administration, oxygen therapy will continue with a simple face mask at a flow rate of 5 to 10 liters per minute based on the patients' needs.

Category

Prevention

2

Description

Control Group: In the control group, after extubation, patients will receive oxygen via nasal cannula at 6-10 L/min, titrated to maintain oxygen saturation above 90%.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Ali Ibn Abi Talib (AS) hospital in ZahedanCity

Full name of responsible person

Abdolrab Dorazehi

Street address

Ali Ibn Abi Talib (AS) Hospital, in front of Imam Khomeini Mosque, Persian Gulf Highway, Zahedan City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

Ebrahim Kord

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Zahedan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Zahedan University of Medical Sciences
Full name of responsible person
Abdolrab Dorazehi
Position
Student of Bachler of Critical Care Nursing
Latest degree
Bachelor
Other areas of specialty/work
Nursery
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
After completing the study, data extraction and analysis will be published as an article.
When the data will become available and for how long
After completing the study, data extraction and analysis will be published as an article.
To whom data/document is available
After completing the study, data extraction and analysis will be published as an article.
Under which criteria data/document could be used
After completing the study, data extraction and analysis will be published as an article.
From where data/document is obtainable
After completing the study, data extraction and analysis will be published as an article.
What processes are involved for a request to access data/document
After completing the study, data extraction and analysis will be published as an article.
Comments