Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

The prevention effect of new oxygenation device versus nasal cannula in increasing exhalation co2

Protocol summary

Study aim
Determining the amount of exhaled carbon dioxide and the percentage of peripheral oxygen saturation

Design
This clinical trial will be performed on 200 patients with a control group in parallel and single-blind groups. Assignment of patients in each group based on simple randomization, phase 1 with the help of randomization website, and number assignment to patients will be done.

Settings and conduct
This study is performed in torfeh hospital with informed consent, under local anesthesia and sedation for blepharoplasty surgery. Based on simple randomization, one side of the blind is divided into two groups of 100 people by computer. In group A, a new oxygenation device is used and in group B, nasal cannula is used. In both groups, the oxygen flow is 4 liters per minute.Etco2 by capnograph and Spo2 via pulse oximetry are measured.

Participants/Inclusion and exclusion criteria
American society of Anesthesiologists (ASA) class 1 to 2 will be included and patients with chronic pulmonary, cardiovascular, renal, and sever chest deformity or patients without the possibility of cooperation such as language problems or deafness, psychiatric disorders and previous upper airway surgeries will be excluded.

Intervention groups
100 blepharoplasty surgery patients under local anesthesia and sedation in the intervention group receive oxygen flow at the rate of 4 liters per minute from new oxygenation device.

Main outcome variables
End-Tidal CO2, Peripheral oxygen saturation

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210216050379N3**
Registration date: **2022-05-15, 1401/02/25**
Registration timing: **registered_while_recruiting**

Last update: **2022-05-15, 1401/02/25**
Update count: **0**

Registration date
2022-05-15, 1401/02/25

Registrant information

Name
Hamidreza Azizifarsani

Name of organization / entity

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Iran (Islamic Republic of)

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+98 21 2274 1174

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-05-10, 1401/02/20

Expected recruitment end date
2022-11-11, 1401/08/20

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The prevention effect of new oxygenation device versus nasal cannula in increasing exhalation co2

Public title

The effect of New oxygenation device on respiratory function enhancment.

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Local blepharoplasty surgery via intravenous sedation

Exclusion criteria:

Chronic pulmonary, cardiovascular, renal, hepatic dysfunction or psychiatric disorders. Sever chest wall deformity. Patients without the possibility of cooperation such as language problems or deafness.

Age

From **30 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **200**

Randomization (investigator's opinion)

Randomized

Randomization description

200 patients scheduled for blepharoplasty surgery by simple randomization located in two groups:nasal canulla and new oxygenation device .the method of randomization and concealment was as follows:we started from the number1 to 200 and assigned the odd numbers to the nasal canulla group and the even numbers to the new ventilation device.

Blinding (investigator's opinion)

Single blinded

Blinding description

The researcher and the person conducting the measurement and data collection do not know the patient grouping.

Placebo

Not used

Assignment

Parallel

Other design features

The device was tested by studying cataract patients and had significant results and was accepted at the World Anesthesia Congress in Prague.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of shahid beheshti university of medical science

Street address

Medical school, Shahid Beheshti University of Medical Sciences, Arabi Ave, Daneshjoo Blvd, Velengak, Tehran, Iran.

City

Tehran

Province

Tehran

Postal code

1983963113

Approval date

2022-01-10, 1400/10/20

Ethics committee reference number

IR.SBMU.MSP.REC.1400.680

Health conditions studied

1

Description of health condition studied

The preventive effect of new oxygenation device versus nasal canulla in increasing exhalation Co2

ICD-10 code

ICD-10 code description

موضوع ما بیماری نیست

Primary outcomes

1

Description

Measurement of End tidal co2 and peripheral oxygen saturation

Timepoint

IN 0, 5, 10, 15, 20, 25, 30, 35, 40, 50, 60, 70, 80, 90 minutes

Method of measurement

Capnography and Pulse oximetery device

Secondary outcomes

1

Description

Respiratory Rate

Timepoint

In 0, 5, 10, 15, 20, 25, 30, 35, 40, 50, 60, 70, 80 and 90 minutes

Method of measurement

Inspection ,counting the number of inhales and exhales in the mentioned minutes

2

Description

Blood pressure

Timepoint

In 0, 5, 10, 15, 20, 25, 30, 35, 40, 50, 60, 70, 80, 90 minutes

Method of measurement

Sphygmomanometer (non invasive)

3

Description
Agitation and restlessness
Timepoint
In 0, 5, 10,15, 20, 25, 30, 35, 40, 50, 60, 70, 80, 90 minutes
Method of measurement
Richmond Agitation -sedation Questionnaire

Intervention groups

1

Description
Intervention group: Patients in intervention group (A) receive 4 liters per minute of oxygen by a new oxygenation device that is sterile, reusable and washable. The polylactic acid weighs 110 grams and then placed on the patient's chest and with complete cardio-respiratory monitoring (EKG, SPO2, End Tidal co2, BP, RR) the patient's hemodynamic status and with the Richmond questionnaire, sedation status of The onset of the operation is measured and recorded up to 10 minutes after the operation, then the results are given to a statistician to analyze the data are obtained. P-value less than 0.05 will be considered significant.
Category
Prevention

2

Description
Control group: Patients in this group (B) are traditionally treated using a disposable nasal cannula made by Supao Company with a flow of 4 liters per minute of oxygen.Capnotrack is attached to the nasal cannula and exhaled carbon dioxide is transferred to the capnograph, and as intervention group, complete cardio respiratory monitoring is performed.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Torfeh Hospital
Full name of responsible person
Hamidreza Azizi farsani
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
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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
Shahid Beheshti University of Medical Sciences
Proportion provided by this source
50
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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Hamidreza Azizifarsani
Position
Assistant professor
Latest degree
Specialist

Other areas of specialty/work
Anesthesiology
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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
Not applicable
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Individual data is shared after it is unidentifiable and the main outcome
When the data will become available and for how long
From May 1402 onwards
To whom data/document is available
Professors and Medical students
Under which criteria data/document could be used
For more research
From where data/document is obtainable
Contact Hamidreza Azizifarsani by email
What processes are involved for a request to access data/document
up to 10 days after the call
Comments