Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Effect of Nasal High-Flow oxygen therapy on respiratory performance in ICU after bariatric surgery

Protocol summary

Study aim
Nasal Flow High Oxygen Therapy Effect on Respiratory Quality in Patient Care Units after Surgery

Design
Clinical trial with CPAP, HFNT, with parallel groups, blind, randomized,

Settings and conduct
Patients undergoing laparoscopic slashing gastrectomy surgery referring to Shahid Modarres Hospital are divided into two groups. The cpap group, after which the patients undergo emergency recovery at the CPAP with a mask (CmH2O) of 8-12, and the HFNT group that the patients after Extubation in recovery is immediately superimposed on oxygen therapy through HIGH FLOW NASAL (OPTIFLOW) with FIO2: 50% and FLOW45-55 L / MIN.

Participants/Inclusion and exclusion criteria
Entry: Includes people between 18 and 65 years of age BMI> 35 Obesity in the last 3 years without hormone problems and STOP BANG> 3 (16) Exit: Includes nasal defect, such as nasal polyps, septal perforation (acute or chronic pulmonary disease, an episode hemorrhage that requires transfusion).

Intervention groups
Group CPAP: After recovery, patients are immediately exposed to CPAP mask (CmH2O) 8-12. And in the ICU, the surgery lasts for at least 8 hours. HFNT group: Patients after recovery in recovery are immediately put on oxygen therapy through HIGH FLOW NASAL (OPTIFLOW) with FIO2: 50% and FLOW45-55 L / MIN. And at ECU surgery is continued for at least 8 hours

Main outcome variables
PaCO2;PaO2;PEFR;AHI;(m-RAS)

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20150107020592N21**
Registration date: **2019-06-23, 1398/04/02**
Registration timing: **registered_while_recruiting**

Last update: **2019-06-23, 1398/04/02**
Update count: **0**

Registration date
2019-06-23, 1398/04/02

Registrant information

Name
Seyed Mohammad Reza Hashemian

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 21 2610 9944

Email address
iran.criticalcare@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-03-18, 1397/12/27

Expected recruitment end date
2020-03-17, 1398/12/27

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effect of Nasal High-Flow oxygen therapy on respiratory performance in ICU after bariatric surgery

Public title
Effect of Nasal High-Flow oxygen therapy on respiratory

performance in ICU after bariatric surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

People between 18 and 65 years old BMI>35 The presence of obesity in the last 3 years without hormonal problems STOP BANG>3

Exclusion criteria:

Nasal defects such as nasal polyps, septum perforation Acute or Chronic Pulmonary Patient

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **116**

Randomization (investigator's opinion)

Randomized

Randomization description

The randomization of the two groups is based on the even and the odd numbers, the even numbers belong to the intervention group and The odd numbers belong to patients in the control group..

Blinding (investigator's opinion)

Double blinded

Blinding description

Laboratory, clinical and radiological evidence is collected by people who do not have the type of intervention.The analysis is done by someone else who does not have the type of intervention.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahid Beheshti University of Medical Sciences and Health Services

Street address

SBUMS, Arabi Ave, Daneshjoo Blvd, Velenjak, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1985717443

Approval date

2019-03-17, 1397/12/26

Ethics committee reference number

IR.SBMU.RETECH.REC.1397.1390

Health conditions studied

1

Description of health condition studied

Patients undergoing laparoscopic surgery for gastrectomy

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

PCO2

Timepoint

Every eight hours for a day

Method of measurement

Using ABG

2

Description

PO2

Timepoint

Every eight hours for a day

Method of measurement

Using ABG

3

Description

PEAK expiratory flow rate

Timepoint

After surgery, bariatric

Method of measurement

peak flow meter

4

Description

Apnea–Hypopnea Index

Timepoint

After surgery, bariatric

Method of measurement

Poly Somnography

5

Description

modified radiological atelectasis score

Timepoint

After surgery, bariatric

Method of measurement
نمرات CXR

Secondary outcomes

empty

Intervention groups

1

Description
First Intervention group: After recovery, the patients are immediately treated with CPAP mask (CmH2O) 8-12 and surgical ICU is continued for at least 8 hours.
Category
Treatment - Other

2

Description
Second intervention group: After recovery, the patients immediately receive oxygen therapy through HIGH FLOW NASAL (OPTIFLOW) with FIO2: 50% and FLOW45-55 L / MIN, and they continue to undergo surgery for at least 8 hours.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Modarress Educational Hospital
Full name of responsible person
navid nooraei
Street address
Saadat Abad St.Yadegare Imam Highway,Tehran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Shahid Beheshti University of Medical Sciences
Full name of responsible person
Dr Seyyed Mohamadreza Hashemian
Street address
SBUMS, Arabi Ave, Daneshjoo Blvd, Velenjak, Tehran, Iran
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iran.criticalcare@yahoo.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research, Shahid Beheshti 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
The Edjucational , Research and Treatment center masih daneshvari
Full name of responsible person
Seyed Mohamad Reza Hashemian
Position
Professor
Latest degree
Subspecialist
Other areas of specialty/work
Anesthesiology
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Latest degree
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
I do not have a program

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available