

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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)

Phone

+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

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Saadat Abad St.Yadegare Imam Highway,Tehran

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Email

modarres@sbmu.ac.ir

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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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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Masih Daneshvari Hospital, Darabad Avenue, Shahid Bahonar roundabout, Tehran, Iran

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

Seyed Mohamad Reza Hashemian

Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

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Person responsible for updating data

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Full name of responsible person

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Position

دستیار فوق تخصص ICU

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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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