

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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 (CmH<sub>2</sub>O) 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 FIO<sub>2</sub>: 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 (CmH<sub>2</sub>O) 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 FIO<sub>2</sub>: 50% and FLOW45-55 L / MIN. And at ECU surgery is continued for at least 8 hours

##### Main outcome variables

PaCO<sub>2</sub>; PaO<sub>2</sub>; 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

##### Street address

Saadat Abad St.Yadegare Imam Highway,Tehran

##### City

Tehran

##### Province

Tehran

##### Postal code

1998734383

##### Phone

+98 21 2207 4087

##### Fax

+98 21 2207 4101

##### 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

#### City

Tehran

#### Province

Tehran

#### Postal code

1956944413

#### Phone

+98 21 2912 3100

#### Email

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

##### Street address

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

##### City

Tehran

##### Province

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##### Postal code

1956944413

##### Phone

+98 21 2111 9279

##### Email

iran.criticalcare@yahoo.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

The Educational , Research and Treatment center

**Full name of responsible person**

Seyed Mohamad Reza Hashemian

**Position**

Professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Anesthesiology

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## Person responsible for updating data

### Contact

**Name of organization / entity**

The Educational , Research and Treatment center  
masih daneshvari

**Full name of responsible person**

navid nooraei

**Position**

دستیار فوق تخصص ICU

**Latest degree**

Specialist

**Other areas of specialty/work**

Anesthesiology

**Street address**

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

**City**

Tehran

**Province**

Tehran

**Postal code**

1956944413

**Phone**

+98 21 2912 3100

**Email**

navidnooraei@gmail.com

## 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