

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

16 Sep 2026

### Comparison of the effect of incentive spirometry and deep breathing exercise on hemodynamic indicators and pulmonary complications during and after sleeve surgery.

#### Protocol summary

##### Study aim

Determining the comparative effect of incentive spirometry and deep breathing exercise on hemodynamic indices and pulmonary complications during and after sleeve surgery in Imam Khomeini hospital, Tehran, in 2023

##### Design

Clinical trial with control group, with parallel groups, without blinding, randomized, Study on 75 patients, block randomization was used for randomization.

##### Settings and conduct

Patients who refer to Imam Khomeini hospital in Tehran for sleeve surgery in 2023.

##### Participants/Inclusion and exclusion criteria

Admission: candidate for sleeve surgery, willing to cooperate, ASA1 and ASA2 anesthesia class one and two. with BMI above 35, age range 16 to 76 years old. Withdrawal: patients with severe chest or upper abdominal pain (VAS more than 75).

##### Intervention groups

The first group of the test will use incentive spirometry and the second group will use the deep breathing technique two hours before the operation and two, six and ten hours after the operation, after the procedure and during the surgery, venous blood gas samples, blood pressure, heart rate, arterial blood oxygen saturation and hemodynamics of the patients will be documented and to check the effectiveness the incidence of atelectasis and pneumonia (up to two weeks after the operation) and the length of stay of the patients in the hospital will be checked. In the control group, there will be no special intervention and they will only receive routine hospital cares.

##### Main outcome variables

Hemodynamic indicators include: oxygen saturation, blood pH, heart rate, systolic and diastolic blood pressure, blood CO<sub>2</sub>

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20230223057511N1**

Registration date: **2023-05-08, 1402/02/18**

Registration timing: **registered\_while\_recruiting**

Last update: **2023-05-08, 1402/02/18**

Update count: **0**

##### Registration date

2023-05-08, 1402/02/18

##### Registrant information

##### Name

Fereshteh Farzanmehr

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2208 6052

##### Email address

fereshteh.farzanmehr@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-02-20, 1401/12/01

##### Expected recruitment end date

2023-07-22, 1402/04/31

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

Comparison of the effect of incentive spirometry and deep breathing exercise on hemodynamic indicators and pulmonary complications during and after sleeve surgery.

## Public title

Investigating the effect of incentive spirometry and deep breathing exercise on sleeve surgery

## Purpose

Prevention

## Inclusion/Exclusion criteria

### Inclusion criteria:

Candidate patients for sleeve surgery  
Willing to cooperate  
ASA level one or two  
Having a BMI above 35  
Age range from 16 to 76 years

### Exclusion criteria:

Patients with severe chest or upper abdominal pain (VAS more than 75).

## Age

From **16 years** old to **76 years** old

## Gender

Both

## Phase

N/A

## Groups that have been masked

No information

## Sample size

Target sample size: **75**

## Randomization (investigator's opinion)

Randomized

## Randomization description

For this research, before the start of the study, after obtaining informed consent before the operation, the patients are referred continuously and available, and with the block randomization method, they are divided into three groups: incentive spirometry (I), deep breathing exercise (D), and control. (C) or routine will be assigned. The blocks of this study are 6 (II, DD, CC) which will create 27 states, first determine the possible states of these 6 letters inside the blocks and then randomly Simple and by using random numbers table number 17, the number of blocks that will complete the number of samples will be determined (1 - 27), in this way the type of intervention is determined based on the desired letters with the number of each patient and in a master sheet will be kept and the continuous entry number of the patients will be written on the envelope, and the type of intervention or control will be specified inside the envelope. Gradually, according to the presence of eligible patients, the relevant envelope is returned and the type of intervention inside the non-transparent envelope is determined and the desired technique is performed.

## 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 Mazandaran University of Medical Sciences

##### Street address

Journal office, Research and Technology Deputy, Third Floor, Building No2, Mazandaran University of Medical Sciences and Healthcare Services, Moalem Square, Sari

##### City

Sari

##### Province

Mazandaran

##### Postal code

1295498972

#### Approval date

2023-04-08, 1402/01/19

#### Ethics committee reference number

IR.MAZUMS.REC.1402.024

## Health conditions studied

### 1

#### Description of health condition studied

Sleeve surgery patients

#### ICD-10 code

E66.01

#### ICD-10 code description

Morbid (severe) obesity due to excess calories

## Primary outcomes

### 1

#### Description

Blood oxygen saturation

#### Timepoint

Blood oxygen saturation is recorded two hours before surgery after using incentive spirometry and deep breathing exercise, during surgery and two, six and ten hours after surgery after using incentive spirometry and deep breathing exercise. The control group is also registered with the same pattern.

#### Method of measurement

The way to measure blood oxygen saturation is by a portable pulse oximetry device.

### 2

#### Description

Heart rate

#### Timepoint

Heart rate is recorded two hours before surgery after

using incentive spirometry and deep breathing exercise, during surgery and two, six and ten hours after surgery after using incentive spirometry and deep breathing exercise. The control group is also registered with the same pattern.

#### **Method of measurement**

The way to measure the heart rate is by a portable pulse oximetry device.

### **3**

#### **Description**

Blood pressure

#### **Timepoint**

Blood pressure is recorded two hours before surgery after using incentive spirometry and deep breathing exercise, during surgery and two, six and ten hours after surgery after using incentive spirometry and deep breathing exercise. The control group is also registered with the same pattern.

#### **Method of measurement**

Blood pressure is measured by a sphygmomanometer.

### **4**

#### **Description**

Blood PH

#### **Timepoint**

The level of blood PH is recorded two hours before the operation after using incentive spirometry and deep breathing exercise, during the operation and two, six and ten hours after the operation after using incentive spirometry and deep breathing exercise. The control group is also registered with the same pattern.

#### **Method of measurement**

Blood PH is determined by venous blood gas analysis.

### **5**

#### **Description**

Blood carbon dioxide

#### **Timepoint**

Blood carbon dioxide level is recorded two hours before the operation after using incentive spirometry and deep breathing exercise, during the operation and two, six and ten hours after the operation after using incentive spirometry and deep breathing exercise. The control group is also registered with the same pattern.

#### **Method of measurement**

Blood carbon dioxide is determined by venous blood gas analysis.

## **Secondary outcomes**

### **1**

#### **Description**

Pneumonia

#### **Timepoint**

The incidence of pneumonia after the surgery is checked by referring to the patient's file and examination of clinical symptoms by an expert up to two weeks.

#### **Method of measurement**

Refer to the patient's file and check the clinical symptoms by the specialist

### **2**

#### **Description**

Atelectasis

#### **Timepoint**

The incidence of atelectasis after the surgery is checked by referring to the patient's file and examination of clinical symptoms by an expert up to two weeks.

#### **Method of measurement**

Refer to the patient's file and check the clinical symptoms by the specialist.

### **3**

#### **Description**

Length of hospitalization

#### **Timepoint**

The length of hospitalization is checked after the patient's discharge and by referring to the patient's file.

#### **Method of measurement**

Referring to the patient's file.

## **Intervention groups**

### **1**

#### **Description**

Intervention group: in the first intervention group, the intervention method is incentive spirometry. In this method, patients are placed in a sitting or semi-sitting position, and an incentive spirometry tube is placed in their mouth. They inhale and then hold their breath for 3-5 seconds and slowly exhale through the mouth as they remove the device. The patient performs this exercise 5 times two hours before the operation, two, six and ten hours after the operation. The average maximum inspiratory volume of the patient is recorded by incentive spirometry.

#### **Category**

Prevention

### **2**

#### **Description**

Control group: in the control group, only routine cares will be done. Usual hospital cares include : drug treatment, checking vital signs, controlling patients' pain and encouraging patients to breathe deeply.

#### **Category**

Prevention

### **3**

#### **Description**

Intervention group: the second intervention group, the intervention method is deep breathing exercise. In this method, the patient is sitting or semi-sitting, taking slow and deep breaths through the nose, at the same time, he presses the upper part of the abdomen with a pillow to reduce the pain. The patient inhales and then holds his

breath for 3 to 5 seconds and exhales through pursed lips by squeezing the abdominal muscles. The patient performs this exercise 5 times two hours before the operation and two, six and ten hours after the operation.

**Category**

Prevention

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Imam Khomeini hospital

**Full name of responsible person**

Fereshteh Farzanmehr

**Street address**

Imam Khomeini Hospital Complex, Dr. Gharib St,  
Keshavarz Blvd, Tehran

**City**

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**Province**

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**Postal code**

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**Phone**

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Imamhospital@tums.ac.ir

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Mazandaran University of Medical Sciences

**Full name of responsible person**

Pedram Ebrahimnejad

**Street address**

Research and Technology Vice-Chancellor, Third  
Floor, Moalem Square, Building No.2, Mazandaran  
University of Medical Sciences and Healthcare  
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1234568952

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jmums@mazums.ac.ir

**Web page address**

http://jmums.mazums.ac.ir

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Mazandaran 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**

Mazandaran University of Medical Sciences

**Full name of responsible person**

Fereshteh Farzanmehr

**Position**

Master Student

**Latest degree**

Master

**Other areas of specialty/work**

Nursery

**Street address**

Num. 136 , Second Floor, C1 Building, Sarvestan  
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**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Mazandaran University of Medical Sciences

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**Position**

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**Latest degree**

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**Person responsible for updating data****Contact****Name of organization / entity**

Mazandaran University of Medical Sciences

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**Position**

Master Student

**Latest degree**

Master

**Other areas of specialty/work**

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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 of study participants is considered and all data can be shared after de-identification of individuals.

**When the data will become available and for how long**

The access period starts 6 months after publication of results

**To whom data/document is available**

Our data will only be available to researchers working in academic and scientific institutions

**Under which criteria data/document could be used**

Our data will only be available to researchers working in academic and scientific institutions. Statistical analysis is possible on the data and they can use email to send requests.

**From where data/document is obtainable**

Applicants can contact Fereshte Farzanmehr at the following address: Email:

Fereshteh.Farzanmehr@gmail.com Postal code:

1468613831 Phone: 09128347148

**What processes are involved for a request to access data/document**

After receiving the request by the researcher, the documents will reach the applicant within two weeks at most.

**Comments**