

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

25 Jul 2026

### Comparison of changes in serum interleukin, in patients with morbid obesity under laparoscopic gastric bypass surgery, before and after general anesthesia with isoflurane and propofol.

#### Protocol summary

##### Summary

The purpose of this study is to compare changes in serum Interleukin, in patients with morbid obesity undergoing laparoscopic gastric bypass surgery, is before and after general anesthesia with isoflurane and propofol. 32 patients undergoing laparoscopic gastric bypass referring to Hazrat Rasoul Hospital as a random, double-blind, without control with placebo and with phase 1-2 trials using block randomization and parallel divided into two groups. Patients should be ASA II -III and have morbid obesity (BMI > = 35 kg / m<sup>2</sup>). Patients with cardiovascular and respiratory diseases, renal failure, diabetes and diseases of the name and the number of white blood cells more than 10 thousand patients are be excluded. After pre-oxygenation, anesthesia induction and patient intubation, as the maintenance of anesthesia during the operation, in first group isoflurane is used and in second group propofol is used intravenously. Then in both groups, interleukin 10 and TNF $\alpha$  by ELISA method is measured.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2015111812642N22**

Registration date: **2015-12-03, 1394/09/12**

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

Last update:

Update count: **0**

##### Registration date

2015-12-03, 1394/09/12

##### Registrant information

##### Name

Majid Golestani Eraghi

##### Name of organization / entity

Shahid Beheshti University Of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 3336 0547

##### Email address

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##### Recruitment status

**Recruitment complete**

##### Funding source

Vice Chancellor for Research, Iran University of Medical Sciences

##### Expected recruitment start date

2015-03-21, 1394/01/01

##### Expected recruitment end date

2015-12-22, 1394/10/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of changes in serum interleukin, in patients with morbid obesity under laparoscopic gastric bypass surgery, before and after general anesthesia with isoflurane and propofol.

##### Public title

Serum interleukin changes in gastric bypass surgery, before and after general anesthesia with isoflurane and propofol .

##### Purpose

Prevention

##### Inclusion/Exclusion criteria

Inclusion criteria: Patients undergoing laparoscopic

gastric bypass; ASA Class II -III; morbid obesity (BMI> = 35 kg / m2); Exclusion criteria: With cardiovascular and respiratory diseases, drug and alcohol abuse, renal failure, liver dysfunction and autoimmune disease, diabetes or asthma disease, regular use of steroids and NSAID; core temperature greater than 37 ° C, the number of cells white More than 10 thousand

#### Age

From **18 years** old to **60 years** old

#### Gender

Both

#### Phase

1-2

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **64**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

#### Blinding (investigator's opinion)

Double blinded

#### Blinding description

#### Placebo

Not used

#### Assignment

Parallel

#### Other design features

Randomization is performed using block randomization.

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Iran University of Medical Sciences

##### Street address

Hemmat Highway

##### City

Tehran

##### Postal code

#### Approval date

2014-06-08, 1393/03/18

#### Ethics committee reference number

105 /145/93/5

## Health conditions studied

### 1

#### Description of health condition studied

Laparoscopic Gastric Bypass

#### ICD-10 code

E66.8

#### ICD-10 code description

Morbid obesity

## Primary outcomes

### 1

#### Description

interleukin 10

#### Timepoint

Before the induction of anesthesia and end of anesthesia

#### Method of measurement

In blood plasma sample, by ELISA, according picogram per milliliter

### 2

#### Description

TNF Alfa

#### Timepoint

Before the induction of anesthesia and end of anesthesia

#### Method of measurement

In blood plasma sample, by ELISA, according picogram per milliliter

## Secondary outcomes

### 1

#### Description

Age

#### Timepoint

Before entering the study

#### Method of measurement

Based on the number of years of life on the basis of year

### 2

#### Description

Height

#### Timepoint

Before enteiring to study

#### Method of measurement

Based on the information in the file and on the basis of centimeter

### 3

#### Description

wieght

#### Timepoint

Before entering to study

#### Method of measurement

Based on the information in the file and on the basis of kilogram

## Intervention groups

### 1

#### Description

In the first group, 1.2% isoflurane is used as a maintenance of anesthesia during surgery.

**Category**  
Prevention

2

**Description**

In the second group, intravenous propofol is used as a maintenance of anesthesia during surgery.

**Category**  
Prevention

**Recruitment centers**

1

**Recruitment center**

**Name of recruitment center**  
Hazrat Rasool Hospital  
**Full name of responsible person**  
Valiollah Hasani  
**Street address**  
Satarkhan Ave  
**City**  
Tehran

**Sponsors / Funding sources**

1

**Sponsor**

**Name of organization / entity**  
Vice chancellor for research, Iran University of Medical Sciences  
**Full name of responsible person**  
Seyed Alijavad Musavi  
**Street address**  
Vice chancellor for research of Iran University of Medical Sciences, Hemmat Highway  
**City**  
Tehran

**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, Iran University of Medical Sciences

**Proportion provided by this source**  
100

**Public or private sector**  
*empty*

**Domestic or foreign origin**  
*empty*

**Category of foreign source of funding**  
*empty*

**Country of origin**

**Type of organization providing the funding**  
*empty*

**Person responsible for general inquiries**

**Contact**

**Name of organization / entity**  
Razi Vaccine and Serum Research Institute  
**Full name of responsible person**  
Seyed Reza Bani Hashemi  
**Position**  
Immunologist  
**Other areas of specialty/work**  
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**Person responsible for scientific inquiries**

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Anesthesiology group of Iran University of Medical Sciences  
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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*