

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 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 / m²). 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 α 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

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Phone

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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 entering 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 kilogeram

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

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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

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Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Anesthesiology group of Iran University of Medical Sciences

Full name of responsible person

Valiollah Hasani

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Anesthesiologist

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Anesthesiology group of Shahid beheshti University of Medical Sciences

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Anesthesiologist

Other areas of specialty/work**Street address**

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Web page address

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