

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

17 Sep 2026

### A Comparative Study on the Effect of Propofol and Isoflurane in Anesthetic Maintenance on Blood Glucose Level During Operation of Patients with Type 2 Diabetes Mellitus in Isfahan

#### Protocol summary

##### Study aim

The purpose of this study is to compare the effects of Propofol and Isoflurane on the level of blood glucose in patients with type 2 diabetes mellitus who are surgical candidates.

##### Design

This clinical trial is randomized, without any control group, community-based, and pragmatic, with parallel groups and triple blind.

##### Settings and conduct

Participants would be selected according to the order of referral to the surgical centers after evaluating the inclusion and exclusion criteria and randomly divided into Isoflurane or Propofol receiving group. After obtaining the full profile, vital signs, blood glucose level, and the oxygen and CO<sub>2</sub> levels of the blood will be recorded before, during and after the surgery up to one hour.

##### Participants/Inclusion and exclusion criteria

Presence of type 2 diabetes mellitus, Being a candidate for an elective surgery with general anesthesia, A duration of more than one hour for the surgical operation

##### Intervention groups

The participants of the first group (Isoflurane) would be first anesthetized with Fentanyl, Atracurium and Thiopental sodium. Isoflurane 1-1.5% in a mixture of 50% oxygen and nitrous oxide (N<sub>2</sub>O) would be used for anesthetic maintenance. In the second group (Propofol), induction of anesthesia will be performed in patients with Fentanyl, Atracurium and Propofol. Propofol will be used at a rate of 9 to 12 milligrams per kilogram of body weight per hour for anesthetic maintenance. Moreover, within an interval (prior to the surgery and up to one hour after surgery), vital signs, blood oxygen and blood glucose levels would be evaluated.

##### Main outcome variables

Blood glucose levels in patients before and after surgery

in milligrams per deciliter

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20170716035104N1**

Registration date: **2018-12-29, 1397/10/08**

Registration timing: **retrospective**

Last update: **2018-12-29, 1397/10/08**

Update count: **0**

##### Registration date

2018-12-29, 1397/10/08

##### Registrant information

##### Name

Roham Nik Khah

##### Name of organization / entity

Medical University of Isfahan

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 3668 6444

##### Email address

admin.ycc@med.mui.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2017-04-04, 1396/01/15

##### Expected recruitment end date

2018-04-09, 1397/01/20

##### Actual recruitment start date

2017-04-04, 1396/01/15

##### Actual recruitment end date

2018-04-19, 1397/01/30

**Trial completion date**  
2018-09-22, 1397/06/31

**Scientific title**  
A Comparative Study on the Effect of Propofol and Isoflurane in Anesthetic Maintenance on Blood Glucose Level During Operation of Patients with Type 2 Diabetes Mellitus in Isfahan

**Public title**  
Effect of Propofol and Isoflurane on Blood Glucose Level in Type 2 Diabetes Mellitus

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Presence of type 2 diabetes mellitus Being a candidate for an elective surgery with general anesthesia The absence of drug allergy The absence of severe liver, kidney, heart or lung disorders An age between 15 and 65 years A duration of more than one hour for the surgical operation  
**Exclusion criteria:**  
Patient's requirement for the prescription of Catecholamines during the anesthesia Not consenting to take part in the study Inability to continue participation in the study

**Age**  
From **15 years** old to **65 years** old

**Gender**  
Both

**Phase**  
2-3

**Groups that have been masked**

- Participant
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

**Sample size**  
Target sample size: **110**  
Actual sample size reached: **110**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
The patients will be selected according to their referral to the surgical centers in this study. Using the random function command of Excell software, random numbers will be assigned to each patient by a person independent of the research team and then he/she prints the numbers on small pieces of paper. Then, the papers will be folded so the page with the numbers could not be seen. After putting the papers into a box, another independent person takes 55 paper pieces from the box and puts them into a section which is known as the Isoflurane group, and the other 55 pieces are put in the section known as the Propofol group.

**Blinding (investigator's opinion)**  
Triple blinded

**Blinding description**

All patients will be blinded to the drugs that are used for their anesthesia. Because of the difference in the intended anesthetic techniques, the clinical caregiver cannot be blinded to the type of intervention he/she is conducting, but due to the concealment of the patient's profile before reading his/her case in the presence of the operating room secretary, the clinical caregiver would not have any knowledge about the patient's profile. The evaluator of the consequences obtains the required information for the study in the presence of the operating room secretary and is blinded to the patient's profile and the technique of anesthesia. The members of the Data Safety and Monitoring Committee, the investigator and the analyst will be blinded to the patient's profile and the drugs he/she receives.

**Placebo**  
Not used

**Assignment**  
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Isfahan University of Medical Sciences

##### Street address

Isfahan University of Medical Sciences, Hezar Jarib Ave., Isfahan, Iran.

##### City

Isfahan

##### Province

Isfahan

##### Postal code

7346181746

#### Approval date

2015-05-29, 1394/03/08

#### Ethics committee reference number

IR.MUI.REC.1394.3.1058

## Health conditions studied

### 1

#### Description of health condition studied

Type 2 diabetes mellitus

#### ICD-10 code

E11

#### ICD-10 code description

Type 2 diabetes mellitus

## Primary outcomes

## 1

### **Description**

Blood glucose levels in patients with type 2 Diabetes Mellitus in milligrams per deciliter

### **Timepoint**

Before surgery and an hour after starting the anesthetic maintenance

### **Method of measurement**

The patient's blood sample will be sent to a reference laboratory to measure blood glucose levels

## **Secondary outcomes**

## 1

### **Description**

Heart rate (beats per minute)

### **Timepoint**

Before surgery, 15th minute of surgery, 30th minute of surgery, 45th minute of surgery, 60th minute of surgery and in the recovery

### **Method of measurement**

Beat count by palpating distal radius pulse

## 2

### **Description**

Mean atrial pressure (mm Hg)

### **Timepoint**

Before surgery, 15th minute of surgery, 30th minute of surgery, 45th minute of surgery, 60th minute of surgery and in the recovery

### **Method of measurement**

Clinical mercury manometer

## 3

### **Description**

Peripheral capillary oxygen saturation (percentage)

### **Timepoint**

Before surgery, 15th minute of surgery, 30th minute of surgery, 45th minute of surgery, 60th minute of surgery and in the recovery

### **Method of measurement**

Pulse oximetry

## 4

### **Description**

Body temperature (Celsius degree)

### **Timepoint**

Before surgery, 15th minute of surgery, 30th minute of surgery, 45th minute of surgery, 60th minute of surgery and in the recovery

### **Method of measurement**

Mercury thermometer

## 5

### **Description**

End-Tidal Carbon dioxide level (mm Hg)

### **Timepoint**

Before surgery, 15th minute of surgery, 30th minute of surgery, 45th minute of surgery, 60th minute of surgery and in the recovery

### **Method of measurement**

Capnography

## **Intervention groups**

## 1

### **Description**

The first intervention group (Isoflurane) would be first anesthetized with Fentanyl 2 micrograms per kilogram, Atracurium 0.6 milligrams per kilogram and Thiopental sodium 5 milligrams per kilogram of the body weight. Isoflurane 1-1.5% in a mixture of 50% oxygen and nitrous oxide (N2O) would be used for anesthetic maintenance.

### **Category**

Treatment - Drugs

## 2

### **Description**

In the second intervention group (Propofol), induction of anesthesia will be performed in patients with Fentanyl 2 micrograms per kilogram, Atracurium 0.6 milligrams per kilogram and Propofol 2 milligrams per kilogram of the body weight. Propofol will be used at a rate of 9 to 12 milligrams per kilogram of body weight per hour for anesthetic maintenance.

### **Category**

Treatment - Drugs

## **Recruitment centers**

## 1

### **Recruitment center**

#### **Name of recruitment center**

Saint Zahra hospital

#### **Full name of responsible person**

Mohammad Golparvar

#### **Street address**

Saint Zahra hospital, Sofe Blvd., Shahid Keshvari highway

#### **City**

Isfahan

#### **Province**

Isfahan

#### **Postal code**

8174675731

#### **Phone**

+98 31 3620 2020

#### **Email**

alzahra@mui.ac.ir

#### **Web page address**

<http://alzahra.mui.ac.ir>

## 2

### **Recruitment center**

**Name of recruitment center**

Ayatol'a Kashani hospital

**Full name of responsible person**

Mohammad Golparvar

**Street address**Ayatol'a Kashani hospital, Saheb Rowzat Ave.,  
Ayatol'a Kashani Blvd.**City**

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Kashani@mui.ac.ir

**Web page address**<http://kashani.mui.ac.ir>**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Shaghayegh Haghjoo Javanmard

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sh\_haghjoo@med.mui.ac.ir

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Esfahan 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**

Esfahan University of Medical Sciences

**Full name of responsible person**

Mohammad Golparvar

**Position**

Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Anesthesiology

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golparvar@med.mui.ac.ir

**Web page address**<http://medmail.mui.ac.ir/oldsite/index.php/2012-03-14-06-46-37/2052-%D8%AF%DA%A9%D8%AA%D8%B1-%D9%85%D8%AD%D9%85%D8%AF-%DA%AF%D9%84%D9%BE%D8%B1%D9%88%D8%B1.html>**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Mohammad Golparvar

**Position**

Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Anesthesiology

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**Phone**

+98 31 3270 9537

**Email**

Far333zadmalekzadeh@yahoo.com

## Person responsible for updating data

**Contact****Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Mohammad Farzad Malekzadeh

**Position**

Physician

**Latest degree**

Medical doctor

**Other areas of specialty/work**

General Practitioner

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## Sharing plan

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

Undecided - It is not yet known if there will be a plan to make this available

**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