

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jul 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 CO₂ 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 (N₂O) 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)

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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

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2

Recruitment center

Name of recruitment center

Ayatol'a Kashani hospital

Full name of responsible person

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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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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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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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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