Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Comparison of total intravenous and inhalational anesthesia effect on peri-operative blood glucose levels in diabetic patients undergoing gynecologic surgery

Protocol summary

Summary

Surgeries may trigger the stress response. This response includes hemodynamic, metabolic, and hormonal changes which may alter the blood glucose level. The aim of this study, is to investigate the changes of blood glucose levels in diabetic patients and compare them in two methods of total intravenous (TIVA) or inhalational anesthesia. In this single center, randomized and double-blind clinical trial, diabetic patients with American society of anesthesiologists (ASA) class II or III, undergoing gynecologic surgery using two methods of total intravenous (study group) or inhalational (control group) anesthesia will be enrolled and patients with diabetic neuropathy or severe hepatic disorders will be excluded. The perioperative blood glucose levels was considered the primary endpoint, and was used to estimate the sample size. It was calculated that sample size of 30 patients in each group. Blood glucose levels, vital signs, and hemodynamic data were assessed prior to the surgery incision and each 30 min during surgery, until the end of operation and in the post anesthesia care unit (PACU). Perioperative complications also are recorded.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201608187013N13**
Registration date: **2016-10-20, 1395/07/29**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-10-20, 1395/07/29

Registrant information

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Tabriz University of Medical Sciences

Expected recruitment start date

2016-08-15, 1395/05/25

Expected recruitment end date

2017-04-13, 1396/01/24

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of total intravenous and inhalational anesthesia effect on peri-operative blood glucose levels in diabetic patients undergoing gynecologic surgery

Public title

Effect of anesthesia method on peri-operative blood glucose levels in diabetic patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients candidate to gynecologic

surgery; patients undergoing general anesthesia with endotracheal intubation. Exclusion criteria: Emergence surgery; history of renal disease due to diabetic neuropathy; history of hepatic disease; history of allergy to propofol; history of steroid or beta adrenergic therapy

Age
No age limit

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
Using sealed envelope method, patients were randomly assigned to study group (n = 30), and control group (n = 30) using a computer-generated randomization list. The study is designed double blinded and none of the patients know about their anesthetic medications, as well as one researcher unaware of cases and grouping, fills checklists. An anesthesiologist is aware of the number of cases and grouping, and also the anesthetic medications.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of the research and technology department, Tabriz University of Medical sciences

Street address
Vice Chancellor for Research, Building No. 2 Tabriz University of Medical Sciences, Golgasht Street

City
Tabriz

Postal code

Approval date
2016-08-02, 1395/05/12

Ethics committee reference number
IR.TBZMED.REC.1395.403

Health conditions studied

1

Description of health condition studied
Perioperative blood glocuse levels

ICD-10 code
T88.7

ICD-10 code description
Unspecified adverse effect of drug or medicament

Primary outcomes

1

Description
Blood glocuse lavels

Timepoint
Prior to induction of anesthesia, after surgical incision, every 30 min until the end of surgery, and in post anesthesia care unit (PACU)

Method of measurement
By glucometer

Secondary outcomes

1

Description
Perioperative complications such as hypoglycemia, nausea, myocardial infarction and etc.

Timepoint
Intraoperative and during 24 hours after operation

Method of measurement
Clinical document

Intervention groups

1

Description
In study group: after the standard induction of general anesthesia, for maintenance of anesthesia، intravenous anesthetics will be administered (infusion of propofol 50-150 microgram per kilogram body weight in minute and remifentanil 0.1-1 microgram per kilogram body weight in minute combined with 100 precent oxygen).

Category
Treatment - Other

2

Description
In control group: after the standard induction of general anesthesia, for maintenance of anesthesia inhalation anesthetics will be administered (isoflurane 0.5-1 MAC and 50 percent nitrous oxide in oxygen).

Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Al-Zahra Medical Education Center
Full name of responsible person
Dr. Simin Atashkhoei
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Al-Zahra Hospital, Sought Artesh Street
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for Research, Tabriz University of Medical Scienses
Full name of responsible person
Dr. Rashidi
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Vice chancellor for research, Building No. 2 Tabriz University of Medical Sciences, Golgasht Street
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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
Vice Chancellor for Research, Tabriz University of Medical Scienses
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

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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