Clinical Trial Protocol
Iranian Registry of Clinical Trials

26 Jun 2026

Comparing changes in blood glucose level during and after cataract surgery with light sedation using propofol-fentanyl and midazolam-fentanyl in diabetic patients

Protocol summary

Summary

This study was performed in order to evaluate blood glucose changes in two light sedation methods of midazolam plus fentanyl and propofol + fentanyl. 35 years old or older patients who had diabetes type two (for at least a year) and were candidates for cataract surgery and gave consent to join the study were evaluated. Patients who became hemodynamically unstable or expired during the study, patients who presented clotting or bleeding disorders and patients who had the need for changing to general anesthesia were excluded from the study. This study was performed on 80 diabetic patients and their light sedation method during cataract surgery was midazolam plus fentanyl in one group and propofol plus fentanyl in the other group and changes in blood glucose level were evaluated.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201501126115N2**
Registration date: **2015-01-29, 1393/11/09**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2015-01-29, 1393/11/09

Registrant information

Name

Mojtaba Rahimi Varposhti

Name of organization / entity

Esfahan medical university

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Isfahan University of Medical Sciences

Expected recruitment start date

2013-08-01, 1392/05/10

Expected recruitment end date

2014-02-28, 1392/12/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing changes in blood glucose level during and after cataract surgery with light sedation using propofol-fentanyl and midazolam-fentanyl in diabetic patients

Public title

Blood glucose level changes by propofol & midazolam

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: Age of more than 35 years old; Having Diabetes type 2 for at least one-year; Being a candidate for cataract surgery; Patient's consent to join the study
Exclusion criteria: Hemodynamically unstable patients (need for vasopressors during the study); Dying before the end of the intervention; Occurrence of clotting and bleeding disorders during the study; Need for general anesthesia because of surgery's complications and circumstances

Age
From **35 years** old
Gender
Both

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **80**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features
80 diabetic candidates for cataract surgery who had all the inclusion criteria and consented to join the study, underwent cataract surgery using two methods of Propofol + Fentanyl and Midazolam + Fentanyl for light sedation by the same anesthesiologist (M.R.), and completed their follow-up. Data were collected prospectively. All patients had cataracts and underwent Phacoemulsification surgery

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Isfahan University of Medical Sciences
Street address
Daneshgah st.
City
Isfahan
Postal code
Approval date
2013-05-19, 1392/02/29
Ethics committee reference number
392124

Health conditions studied

1

Description of health condition studied
Non-insulin-dependent diabetes mellitus
ICD-10 code
E11
ICD-10 code description
Non-insulin-dependent diabetes of the young

Primary outcomes

1

Description
Blood glucose level
Timepoint
30 minutes prior to the surgery, each 15 minutes during surgery and at the end of surgery
Method of measurement
Glucometer

Secondary outcomes

1

Description
Heart rate
Timepoint
30 minutes prior to the surgery, each 15 minutes during surgery and at the end of the surgery
Method of measurement
Monitoring

2

Description
Blood pressure
Timepoint
30 minutes prior to the surgery, each 15 minutes during surgery and at the end of the surgery
Method of measurement
Monitoring

3

Description
Respiratory rate
Timepoint
30 minutes prior to the surgery, each 15 minutes during surgery and at the end of the surgery
Method of measurement
Monitoring

4

Description
Oxygen saturation
Timepoint
30 minutes prior to the surgery, each 15 minutes during surgery and at the end of the surgery
Method of measurement
Monitoring

5

Description
Coughs
Timepoint
Each 15 minutes during surgery
Method of measurement
Observation

6

Description
Fighting with ventilator
Timepoint
Each 15 minutes during surgery
Method of measurement
Observation

7

Description
Apnea
Timepoint
Each 15 minutes during surgery
Method of measurement
Monitoring

8

Description
Agitation
Timepoint
Each 15 minutes during the surgery and at the end of the surgery
Method of measurement
Observation

9

Description
Anxiety
Timepoint
Each 15 minutes during the surgery and at the end of the surgery
Method of measurement
Observation

10

Description
Weakness
Timepoint
Each 15 minutes during the surgery and at the end of the surgery
Method of measurement
Observation

11

Description
Headache
Timepoint
Each 15 minutes during the surgery and at the end of the surgery
Method of measurement
Observation

12

Description
Vertigo
Timepoint
Each 15 minutes during the surgery and at the end of the surgery
Method of measurement
Observation

13

Description
Nausea
Timepoint
Each 15 minutes during the surgery and at the end of the surgery
Method of measurement
Observation

14

Description
Vomiting
Timepoint
Each 15 minutes during the surgery and at the end of the surgery
Method of measurement
Observation

15

Description
Diuresis
Timepoint
Each 15 minutes during the surgery and at the end of the surgery
Method of measurement
Observation

16

Description
Respiratory distress
Timepoint
Each 15 minutes during the surgery and at the end of the surgery
Method of measurement
Observation

17

Description
Arrhythmia
Timepoint
Each 15 minutes during the surgery and at the end of the surgery
Method of measurement
Monitoring

Intervention groups

1

Description
Light sedation was performed using midazolam and fentanyl.
Category
Treatment - Drugs

2

Description
Light sedation was pefromed using propofol and fentanyl.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Feiz center
Full name of responsible person
Street address
Soroush st.
City
Isfahan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Isfahan University of Medical Sciences
Full name of responsible person
Vice-chancellor for research
Street address
Daneshgah st.
City
Isfahan
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Isfahan 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
Isfahan University of Medical Sciences
Full name of responsible person
Pooyan Khalighinejad
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Person responsible for scientific inquiries

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Person responsible for updating data

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Phone
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Email
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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