

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)

Phone

+98 31 3792 1532

Email address

rahimi@med.mui.ac.ir

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 performed 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

Position

Medical Student

Other areas of specialty/work

Street address

Daneshgah st.

City

Isfahan

Postal code

Phone

+98 31 3668 0042

Fax

Email

pooyankh@outlook.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Isfahan University of Medical Sciences

Full name of responsible person

Mojtaba Rahimi

Position

Anesthesiologist

Other areas of specialty/work

Street address

Soroush st. , Feiz hospital

City

Isfahan

Postal code

Phone

+98 31 3668 0042

Fax

Email

Rahimi@med.mui.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Isfahan University of Medical Sciences

Full name of responsible person

Mojtaba Rahimi

Position

Anesthesiologist

Other areas of specialty/work

Street address

Soroush st. , Feiz hospital

City

Isfahan

Postal code

Phone

Fax

Email

Rahimi@med.mui.ac.ir

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