

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jun 2026

Comparison of glargine insulin and Regular insulin on quality of perioperative glucose control in type2 diabetic patient undergoing vitrectomy under general anesthesia

Protocol summary

Study aim

The aim of current study is to comparison of glargine insulin and Regular insulin on quality of perioperative glucose control in type 2 diabetic patient undergoing vitrectomy under general anesthesia.

Design

Clinical trial study, with parallel groups, double blinded, randomized

Settings and conduct

80 eligible patients were selected by using randomization method was performed randomly per muted blocks and based on online randomization software randomly and assigned to one of the groups receiving glargine insulin (intervention) or receiving regular insulin (control). All long-term oral and long-acting insulin medications stop the day before surgery. In the morning, the blood sample was checked for potassium and fasting blood glucose and fasting blood capillary blood flow and the patients received subcutaneous glargine insulin or subcutaneous insulin in accordance with the study group. After the start of surgery, every 30 to 45 minutes, capillary blood glucose is checked by glucometer and marked with vital signs. 2 and 4 hours after surgery, capillary blood glucose is also checked. All blood glucose, incidence of hypoglycemia, dose required for regurgitation and duration of surgery are included in the relevant doses.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age 30-70 years old, Duration of diabetes more than 3 months, New York Heart Association (NYHA) Classification 1 or 2. Exclusion criteria: Diabetic ketoacidosis or its history, Renal failure, Liver failure, Hypoglycemia episodes in a hospital, Hyperglycemia without a history of diabetes, Pregnancy, Patients or psychiatric disorders that can not provide information. Corticosteroid use, Infection and sepsis, BMI> 35

Intervention groups

Intervention group: Patients received Glargine insulin during surgery Control group : Patients received Regular insulin during surgery

Main outcome variables

Blood Glucose.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141127020112N8**

Registration date: **2018-12-27, 1397/10/06**

Registration timing: **retrospective**

Last update: **2018-12-27, 1397/10/06**

Update count: **0**

Registration date

2018-12-27, 1397/10/06

Registrant information

Name

Pooya Derakhshan

Name of organization / entity

Birjand Univesity of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 56 3234 1410

Email address

pooya_derakhshan@bums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-08-11, 1396/05/20

Expected recruitment end date

2018-08-11, 1397/05/20

Actual recruitment start date

2017-09-03, 1396/06/12

Actual recruitment end date

2018-08-16, 1397/05/25

Trial completion date

2018-09-08, 1397/06/17

Scientific title

Comparison of glargine insulin and Regular insulin on quality of perioperative glucose control in type2 diabetic patient undergoing vitrectomy under general anesthesia

Public title

Comparison of glargine insulin and Regular insulin on quality of perioperative glucose control

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age: 30-70 years old Duration of diabetes for more than three months New York Heart Association (NYHA) class 1 or 2

Exclusion criteria:

Diabetic ketoacidosis or its history Renal failure Liver failure Hypoglycemia episodes in a hospital Hyperglycemia without a history of diabetes Pregnancy Patients or psychiatric disorders that can not provide information Corticosteroid use Infection and sepsis BMI more than 35

Age

From **30 years** old to **70 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **80**

Actual sample size reached: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomly assigned to intervention and control groups. The randomization method was performed randomly per muted blocks and based on online randomization software.

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients and the person evaluating the treatment outcome will be blinded to the allocated groups.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Iran University of Medical Sciences

Street address

Iran University of Medical Sciences., next to Milad Tower., Hemmat Highway

City

Tehran

Province

Tehran

Postal code

1449614535

Approval date

2017-07-15, 1396/04/24

Ethics committee reference number

IR.IUMS.FMD.REC 1396.9411174022

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

Timepoint

Every 45 minutes during surgery

Method of measurement

Glucometry

Secondary outcomes**1****Description**

Blood potassium

Timepoint

2 and 4 hours after surgery

Method of measurement

Blood test

Intervention groups

1

Description

Intervention group: Patients received Glargine insulin (2/3 of the total dose of insulin) during surgery

Category

Treatment - Drugs

2

Description

Control group: Patients received Regular insulin (Unit=glucose/150) during surgery

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Rasool Akram Hospital

Full name of responsible person

Pooya Derakhshan

Street address

Hazrat-E-Rasool Hospital, Iran University of Medical Sciences, Niayesh St., Sattarkahn Ave., Tehran,

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Seyed Kazem Malakuti

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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

Iran 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

Iran University of Medical Sciences

Full name of responsible person

Pooya Derakhshan

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

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Full name of responsible person

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Latest degree

Specialist

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Person responsible for updating data

Contact

Name of organization / entity

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Position

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Email

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

Yes - There is 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

Not applicable

Title and more details about the data/document

We have not yet set a conclusion

When the data will become available and for how long

We have not yet set a conclusion

To whom data/document is available

We have not yet set a conclusion

Under which criteria data/document could be used

We have not yet set a conclusion

From where data/document is obtainable

We have not yet set a conclusion

What processes are involved for a request to access data/document

We have not yet set a conclusion

Comments