Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparision of glargine insulin and Regular insulin on quality of perioperative glucose control in type2 diabetic patient undergoing viterectomy 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 viterectomy 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)

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+98 56 3234 1410

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

Public title
Comparision 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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Iran University of Medical Sciences., next to Milad Tower., Hemat Highway
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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 updating data

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Position

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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

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