

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Investigation of the effect of administration of Metformin before surgery on controlling postoperative hyperglycemia in non-diabetic patients

Protocol summary

Registration timing: **retrospective**

Study aim

Determining the effect of Metformin administration before surgeries on control of hyperglycemia

Last update: **2022-04-24, 1401/02/04**

Update count: **0**

Design

Clinical trial for two parallel groups (treatment and control) blinded accidentally in the second phase for 176 patients

Registration date

2022-04-24, 1401/02/04

Settings and conduct

Surgery cases of Imam Reza Hospital of Mashhad

Registrant information

Name

Arash Peivandi Yazdi

Name of organization / entity

Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 51 1852 5209

Email address

peivandia@mums.ac.ir

Participants/Inclusion and exclusion criteria

Entry requirements: Non-diabetic patients ASA class I, II
Candidates for orthopedic surgery hospitalized in Imam Reza (AS) Hospital in Mashhad in 1399 will be included in the project
No entry conditions: Prohibitions of metformin use, such as acute or chronic renal failure or injury, or a candidate for diagnostic procedures requiring the administration of a contrast agent before and 5 hours after surgery. Dissatisfaction Allergy to metformin
Patients with ASA above grade II Drug addicts
Uncomplicated surgical complication Forcing to use hemodynamic support drugs at any stage of the study
Use non-general anesthesia to perform the procedure
Need re-surgical intervention in the first 24 hours
Diabetic people

Recruitment status

Recruitment complete

Funding source

Intervention groups

Intervention group: Patients receiving metformin who were given 500 mg metformin tablets at half an hour before surgery. Control group: Includes patients who received a placebo half an hour before surgery.

Expected recruitment start date

2020-03-20, 1399/01/01

Expected recruitment end date

2020-12-21, 1399/10/01

Actual recruitment start date

2021-03-21, 1400/01/01

Actual recruitment end date

2021-12-22, 1400/10/01

Trial completion date

2022-03-06, 1400/12/15

Main outcome variables

Blood Sugar

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20111212008384N9**

Registration date: **2022-04-24, 1401/02/04**

Scientific title

Investigation of the effect of administration of Metformin before surgery on controlling postoperative hyperglycemia in non-diabetic patients

Public title

Investigation of the effect of administration of Metformin

before surgery on controlling postoperative hyperglycemia in non-diabetic patients

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
 Non diabetic patients ASA class I or II Candidate for orthopedic surgery in Imam Reza Hospital of Mashhad during 1399 solar year Ages 18 to 80 years
Exclusion criteria:
 Prohibitions of metformin use, such as acute or chronic renal failure or injury, or a candidate for diagnostic procedures requiring the administration of a contrast agent before and 5 hours after surgery Dissatisfaction Allergy to metformin Patients with ASA above grade II Drug addicts Uncomplicated surgical complication Forcing to use hemodynamic support drugs at any stage of the study Use non-general anesthesia to perform the procedure Need re-surgical intervention in the first 24 hours Diabetic people

Age
From **18 years** old to **80 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size
 Target sample size: **176**
 Actual sample size reached: **176**

Randomization (investigator's opinion)
Randomized

Randomization description
 Block randomization has been used. In this method, 44 blocks of 4 are selected through the relevant sites. Then 88 letters A and 88 letters B were prepared. Opaque envelopes were also used for concealment. 176 envelopes were prepared and the letters A and B were placed inside the envelopes, respectively. The envelopes were sealed and given to the patient's recipient. Each patient was given an envelope (in order) at the time of referral, which the patient provided to the physician. The letter A represented the metformin group and the letter B represented the placebo group.

Blinding (investigator's opinion)
Single blinded

Blinding description
 Employees who admitted patients and recorded data did not know patients who received metformin or placebo and were unaware of how individuals were assigned to the two study groups.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of mashhad University of Medical Sciences

Street address

Department of anesthesiology, Imam Reza hospital, Shariati Square

City

mashhad

Province

Razavi Khorasan

Postal code

۹۱۳۷۹۱۳۳۱۶

Approval date

2020-05-19, 1399/02/30

Ethics committee reference number

lr.mums.medical.rec.1399.289

Health conditions studied

1

Description of health condition studied

blood suger

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

blood suger

Timepoint

after surgery then every 6 hours for 24 hours

Method of measurement

Bs glocometr

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: It consisted of 88 patients receiving one metformin tablet (Merck Sante company, France) at a dose of 500 mg half an hour before surgery orally at a time. Blood glucose, creatinine, and BUN were measured before surgery in these patients. Also, immediately after the operation, the creatinine level, BUN, was measured and blood glucose levels were measured at 6-hour

intervals and up to 24 hours after the operation.

Category

Prevention

2

Description

Control group: It consisted of 88 patients who received one placebo tablet orally half an hour before surgery at a time. Blood glucose, creatinine, and BUN were measured before surgery in these patients. Also, immediately after the operation, the creatinine level, BUN, was measured and blood glucose levels were measured at 6-hour intervals and up to 24 hours after the operation (Faculty of Pharmacy, Mashhad University of Medical Sciences provided us with a similar pill to metformin without any special drug effect as a placebo).

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza hospital

Full name of responsible person

Arash Peivandi Yazdi

Street address

Department of anesthesiology, Imam Reza hospital

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Postal code

9137913316

Phone

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Email

PeivandiA@mums.ac.ir

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

مجید غیور مبرهن

Street address

Ghoreishi apartment, Daneshgah street, Mashhad

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Web page address

https://v-research.mums.ac.ir/

Grant name

Vice Chancellor for Research, Mashhad University of Medical Science

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Dr. Arash Peivandi Yazdi

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Dr. Arash Peivandi Yazdi

Position

Assistant Professor
Latest degree
Subspecialist
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Person responsible for updating data

Contact

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Email
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Data can potentially be shared after people are not identified

When the data will become available and for how long

The access period starts 6 months after the results are published

To whom data/document is available

It will be available to researchers working in academic and scientific institutions

Under which criteria data/document could be used

After correspondence with the scientific person in charge of the project and after the publication of the article, by preserving the intellectual rights of the authors, it is possible to access the data and perform analysis on the information.

From where data/document is obtainable

To request data, you can correspond by email to the person in charge of the scientific plan

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

To request data, you can correspond by email to the person in charge of the scientific plan

Comments