Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Evaluating of the Effect of Oral Administration of Sugar Solution on Intraoperative and Postoperative Blood Glucose Levels in Patients Undergoing Major Gynecological Surgery

Protocol summary

Study aim
To determine the effect of preoperative oral carbohydrate solution on postoperative blood glucose levels in patients undergoing major gynecological surgery

Design
Randomized, double blind, placebo controlled, parallel group clinical trial on 60 patients; randomization was performed using a random number table

Settings and conduct
This single center study is conducted at Shahid Sadoughi Hospital in Yazd. After obtaining informed consent, patients are randomly assigned to two groups. Both patients and outcome assessors are blinded to group allocation.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Women aged 16 to 60 years undergoing major gynecological surgery; American Society of Anesthesiologists physical status class II. Exclusion criteria: American Society of Anesthesiologists class III or higher; history of type 1 or type 2 diabetes mellitus; recent hospitalization within the past two months with dextrose infusion; inability to tolerate oral intake.

Intervention groups
Intervention group: Receiving 100 ml of 50% oral dextrose solution two hours prior to surgery. Control group: Receiving 100 ml of plain oral water as placebo two hours prior to surgery.

Main outcome variables
Blood glucose level

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100102002963N45**
Registration date: **2026-09-27, 1405/07/05**
Registration timing: **prospective**

Last update: **2026-09-27, 1405/07/05**
Update count: **0**

Registration date
2026-09-27, 1405/07/05

Registrant information

Name
Shekoufeh Behdad

Name of organization / entity
Shahid Sadoughi University of Medical Sciences

Country
Iran (Islamic Republic of)

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+98 35 1822 1386

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Recruitment status
recruiting

Funding source

Expected recruitment start date
2026-10-23, 1405/08/01

Expected recruitment end date
2027-01-21, 1405/11/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluating of the Effect of Oral Administration of Sugar Solution on Intraoperative and Postoperative Blood

Glucose Levels in Patients Undergoing Major Gynecological Surgery

Public title
Evaluation of the Effect of Oral Sugar Solution Administration on Blood Glucose Levels in Gynecological Surgery Patients
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
All women aged 16–60 years classified as ASA Physical Status II who are scheduled to undergo major gynecological surgery
Exclusion criteria:
All women aged 16–60 years classified as ASA Physical Status III or higher who are scheduled to undergo major gynecological surgery A diagnosis of either type 1 or type 2 diabetes mellitus Hospitalization within the preceding two months, accompanied by the administration of intravenous dextrose-containing fluids Withdrawal of the patient or her accompanying person from further participation in the study Development of complications related to postoperative hypoglycemia or hyperglycemia Inability to tolerate oral intake for a prolonged period
Age
From **16 years** old to **60 years** old
Gender
Female

Phase
3
Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients will be randomly assigned to two groups using a random number table.
Blinding (investigator's opinion)
Double blinded
Blinding description
Patients and outcome assessors are blinded to the intervention received (sugar solution or water).
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committees of School of Medicine-Shahid Sadoughi University of Medical Sciences
Street address
Faculty of Medicine. Shohadayegomnam Blv.Yazd
City
yazd
Province
Yazd
Postal code
8915887857
Approval date
2025-03-10, 1403/12/20
Ethics committee reference number
IR.SSU.MEDICINE.REC.1403.378

Health conditions studied

1

Description of health condition studied
Elevated blood glucose level
ICD-10 code
R73
ICD-10 code description
Elevated blood glucose level

Primary outcomes

1

Description
Blood glucose level (in milligrams per deciliter)
Timepoint
Before intervention (baseline), at the end of surgery, 1 hour after the end of surgery, and 6 hours after the end of surgery
Method of measurement
Blood glucose monitoring device (Glucometer)

Secondary outcomes

1

Description
Postoperative pain intensity
Timepoint
1 hour and 6 hours after the end of surgery
Method of measurement
Visual Analogue Scale (score 0 to 10)

Intervention groups

1

Description
Intervention group: Patients receive 100 ml of 50% oral dextrose solution two hours before surgery and then undergo major gynecological surgery under general

anesthesia.

Category

Treatment - Drugs

2

Description

Control group: Patients receive 100 ml of water two hours before surgery and then undergo major gynecological surgery under general anesthesia.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Yazd Shahid Sadoughi Hospital

Full name of responsible person

Dr. Shekoufeh Behdad

Street address

Shahid Sadoughi Hospital, Ebnesina Blv, Safayieh, Yazd, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Mehran Karimi

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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

Yazd 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

Yazd University of Medical Sciences

Full name of responsible person

Dr Shekoufeh Behdad

Position

Faculty member and full professor of Shahid Sadoughi University of Medical Sciences, Yazd

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

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Position

Faculty member and full professor of Shahid Sadoughi University of Medical Sciences, Yazd

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Person responsible for updating data

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Full name of responsible person
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Position
Medical Student (Medical Intern)

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Medical doctor

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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
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available