

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jun 2026

Evaluating the effectiveness of adding oral carbohydrates to enhanced recovery after surgery (ERAS) protocol on the postoperative complications in the candidates for bariatric surgery

Protocol summary

Study aim

Determining the effectiveness of adding oral carbohydrates to enhanced recovery after surgery (ERAS) protocol on the postoperative complications in the candidates for bariatric surgery

Design

The ERAS protocol will be implemented as routine for all patients as follows: A. Preoperative: Limit fasting to 6 hours before surgery, reduce opioid use, reduce fluid intake, prescribe anti-emetic drugs before and after surgery, maintain normal blood glucose during the protocol, avoid inserting drains. B- Postoperative: Early oral feeding immediately after full consciousness, early mobilization of the patient to prevent ileus, administration of non-opioid analgesics and improve nutrition C- Follow-up: Checking for complications, need for readmission

Settings and conduct

Candidates for laparoscopic gastric bariatric surgery at Sina Hospital in Tehran and Shahid Bahonar Hospital in Kerman will be included if they meet the study criteria.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1- Consent to participate in the study 2- Age 18 to 65 years 3- Candidate for bariatric surgery due to obesity Exclusion criteria 1- Uncontrolled diabetes mellitus 2- Requiring further surgical intervention 3- Changing the surgical method from Laparoscopy to laparotomy 4- Unprecedented complications during the operation

Intervention groups

Intervention group: Oral 10% dextrose solution 400 cc 6 and 2 hours before surgery Control group: no intervention

Main outcome variables

Duration of hospitalization; Presence and severity of postoperative nausea and vomiting; Electrolyte disturbances; Changes in blood glucose or serum

creatinine; Severity of postoperative pain; Need to prescribe opioids during hospitalization; Wound infection; Postoperative ileus; readmission or intervention within one month.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120516009768N7**
Registration date: **2021-12-15, 1400/09/24**
Registration timing: **registered_while_recruiting**

Last update: **2021-12-15, 1400/09/24**

Update count: **0**

Registration date

2021-12-15, 1400/09/24

Registrant information

Name

Akbar Shafiee

Name of organization / entity

Tehran Heart Center, Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 21 8802 9256

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shafiee@leydenacademy.nl

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-12-11, 1400/09/20

Expected recruitment end date

2022-08-22, 1401/05/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the effectiveness of adding oral carbohydrates to enhanced recovery after surgery (ERAS) protocol on the postoperative complications in the candidates for bariatric surgery

Public title

Evaluating the effectiveness of adding oral carbohydrates to enhanced recovery after surgery (ERAS) protocol on the postoperative complications in the candidates for bariatric surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Consent to participate in the study age 18-65 years
Candidate for bariatric surgery

Exclusion criteria:

Uncontrolled diabetes mellitus
Need for further surgical intervention
Change of surgical method from laparoscopy to laparotomy
Unprecedented adverse events and complications during surgery

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

- Care provider

Sample size

Target sample size: **140**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, we use individual simple randomization using the online Research Randomizer software by producing a series of random numbers. Then the patients will be randomized into two groups by receiving a numbered sealed envelope.

Blinding (investigator's opinion)

Single blinded

Blinding description

The surgeon and the surgical team are not aware of the patient's group and are blinded to it.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of Afzalipour Hospital-
Kerman University of Medical Sciences

Street address

Afzalipour Hospital, Besides Kerman University of
Medical Sciences, Imam Khomeini Blvd, Kerman

City

Kerman

Province

Kerman

Postal code

7616913355

Approval date

2021-10-09, 1400/07/17

Ethics committee reference number

IR.KMU.AH.REC.1400.146

Health conditions studied

1

Description of health condition studied

Morbid Obesity

ICD-10 code

E66.01

ICD-10 code description

Morbid (severe) obesity due to excess calories

2

Description of health condition studied

Bariatric surgery

ICD-10 code

Z98.84

ICD-10 code description

Bariatric surgery status

Primary outcomes

1

Description

Duration of hospitalization

Timepoint

Hospital admission

Method of measurement

Patient's file

2

Description

Postoperative pain

Timepoint

during admission
Method of measurement
VAS score

3

Description
postoperative nausea and vomiting
Timepoint
During admission
Method of measurement
Questionnaire

4

Description
Surgical wound infection
Timepoint
During admission up to 1 months after surgery
Method of measurement
History and physical examination

5

Description
readmission or reoperation
Timepoint
Up to 1 month after surgery
Method of measurement
Follow-up and observation

6

Description
Administration of analgesic or opioid
Timepoint
During hospital admission
Method of measurement
Patient's file

Secondary outcomes

1

Description
Changes in blood glucose
Timepoint
During admission
Method of measurement
Lab test

2

Description
Changes in serum creatinine
Timepoint
During admission
Method of measurement
Lab test

3

Description

postoperative ileus
Timepoint
During admission
Method of measurement
Patient's file

Intervention groups

1

Description
Intervention group: [Oral administration of 400 cc dextrose 20% solution 8 hours before the operation and another 200 cc 2 hours before the operation. We will use commercially available dextrose 20% vials in this study.
Category
Treatment - Other

2

Description
Control group: Routine care with no intervention or placebo
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Sina hospital
Full name of responsible person
Mitra Manavi
Street address
Imam Khomeini ave,
City
Tehran
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Tehran
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1136746911
Phone
+98 21 6634 8500
Email
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2

Recruitment center
Name of recruitment center
Afzalipour hospital
Full name of responsible person
Alireza Amirbeigi
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
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Sina Hospital, Imam Khomeini Ave.
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Knajjari@tums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran 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
Tehran University of Medical Sciences
Full name of responsible person
Mitra Manavi
Position
Fellowship
Latest degree
Subspecialist
Other areas of specialty/work
Laparoscopic surgery
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Person responsible for updating data

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Email

ashafiee@tums.ac.ir

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

Study data will be published anonymously and completely in the form of an article.

When the data will become available and for how long

Available as soon as publication of the results

To whom data/document is available

researchers and physicians

Under which criteria data/document could be used

decision upon request

From where data/document is obtainable

Dr. Mitra Manavi mitramanavi72@gmail.com

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

Formal inquiry

Comments