

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

04 Aug 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)

##### Phone

+98 21 8802 9256

##### Email address

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

##### Province

Tehran

##### Postal code

1136746911

##### Phone

+98 21 6634 8500

##### Email

mitramanavi72@gmail.com

### 2

#### Recruitment center

##### Name of recruitment center

Afzalipour hospital

##### Full name of responsible person

Alireza Amirbeigi

##### Street address

Afzalipour hospital, Imamkhomeni Blvd, Kerman

##### City

Kerman

##### Province

Kerman

##### Postal code

7616913355  
**Phone**  
+98 34 3132 8000  
**Email**  
Ali\_amirbeigi@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Tehran University of Medical Sciences  
**Full name of responsible person**  
Khosro Najjari  
**Street address**  
Sina Hospital, Imam Khomeini Ave.  
**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
1136746911  
**Phone**  
+98 21 6634 8500  
**Email**  
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  
**Street address**  
Sina Hospital, Imam Khomeini Ave.  
**City**

Tehran  
**Province**  
Tehran  
**Postal code**  
1136746911  
**Phone**  
+98 21 6634 8500  
**Email**  
mitramanavi72@gmail.com

## Person responsible for scientific 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  
**Street address**  
Sina Hospital, Imam Khomeni Ave.  
**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
1136746911  
**Phone**  
0982166348500  
**Email**  
mitramanavi72@gmail.com

## Person responsible for updating data

#### Contact

**Name of organization / entity**  
Tehran University of Medical Sciences  
**Full name of responsible person**  
Akbar Shafiee  
**Position**  
Research Associate  
**Latest degree**  
Specialist  
**Other areas of specialty/work**  
Community medicine  
**Street address**  
North Kargar Ave  
**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
1411713138  
**Phone**  
+98 21 8802 9256  
**Fax**  
+98 21 8802 9731

**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**