

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jun 2026

effect of preoperative oral carbohydrate loading on laparoscopic outcome and metabolic respons

Protocol summary

Study aim

Evaluation of the effects of preoperative carbohydrate loading on inflammatory factors and postoperative complications

Design

Participants are then randomly divided into two treatment groups. One of the two groups is fasting as standard before surgery with a normal duration and the other group is undergoing glucose loading as follows. From surgery and then a solution of 400 cc is consumed 2 to 4 hours before surgery. Then albumin, crp, the ratio of the two to each other, as well as the amount of pain and the use of analgesics in 6 hours after surgery, and the same hours the next day and two days after surgery will be measured.

Settings and conduct

Sampling will be done randomly from the study population, which includes inclusion criteria and no exclusion criteria. Sample volume was considered with 95% confidence interval, 0.05 error coefficient and 80% power using Cochran's sample size determination formula

Participants/Inclusion and exclusion criteria

Inclusion criteria include: . Elective case of laparoscopic cholecystectomy . Age over 18 years . Age less than 70 years . Ability to understand and speak in Persian
Exclusion criteria: . History of metabolic diseases such as diabetes . Body mass index below 20 and above 30 . Any disorder requires emergency surgical intervention . Dissatisfaction with the study

Intervention groups

Intervention group: Medical candidate for elective surgery by npo to two hours
Control group: elective surgery information with a npo eight hours

Main outcome variables

Effects of glucose loading on plasma levels of inflammatory factors after surgery (including albumin, CRP to plasma albumin ratio) Prevalence of leakage from surgical drainage in patients who received glucose

loading before surgery. Prevalence of wound complications (including wound opening, wound infection) Evaluation of drainage output in patients with preoperative glucose loading The effect

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200629047952N1**

Registration date: **2021-06-04, 1400/03/14**

Registration timing: **registered_while_recruiting**

Last update: **2021-06-04, 1400/03/14**

Update count: **0**

Registration date

2021-06-04, 1400/03/14

Registrant information

Name

Ehsan Beigi shahr-e babak

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 26 3670 3862

Email address

ehsanbeigi87@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-05-05, 1400/02/15

Expected recruitment end date

2022-03-20, 1400/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

effect of preoperative oral carbohydrate loading on laparoscopic outcome and metabolic respons

Public title

Effect of preoperative oral carbohydrt loading

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age upper18 ,under 70 years Elective surgery cholelithiasis laparoscopy Persian language

Exclusion criteria:

Pregnancy Emergen and urgent surgery Acute and chronic cholecystit Bmi less of 20 and more than 30 Metabolic syndrom

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Use a random number table for verification. Direction Use Random Number Table Start reading the set table numbers The numbers will then be considered for different groups Be. Lay on one of the numbers and in one direction in advance Moves are assigned and assigned numbers to different feature groups I was doing

Blinding (investigator's opinion)

Double blinded

Blinding description

The study will be blinded in two ways. Patients according to type The intervention is blinded as well as the researcher who must enter the data into the checklist Relevant will be blinded to the type of intervention

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethcs committee of alborz university of medical sciences

Street address

Taleghani sq. Alborz uineversity

City

Karaj

Province

Alborz

Postal code

3183966918

Approval date

2021-05-02, 1400/02/12

Ethics committee reference number

IR.ABZUMS.REC.1400.035

Health conditions studied**1****Description of health condition studied**

Npo time

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Pain.

Timepoint

۰,۶,۱۲,۲۴,(houres), 3,7 days

Method of measurement

Vas, cc,need to analgtic

2**Description**

Leakage of drain

Timepoint

0,6,12,24,48 hours

Method of measurement

Mililiter

3**Description**

Vomiting

Timepoint

6,12,24 ,48 hours

Method of measurement

Need to ondansetron

4**Description**

Crp

Timepoint

Day 1 and day 2 at 8 am

Method of measurement

Mg

5**Description**

Albumin

Timepoint

Day 1 day 2 at 8 am

Method of measurement

Mg

Secondary outcomes

empty

Intervention groups**1****Description**

The intervention group is loaded with glucose as follows, first 12.5% solution at a rate of 800 cc in the evening before surgery and then a solution at a rate of 400 cc 2 to 4 hours before surgery. Then albumin, crp, the ratio of the two to each other, as well as the amount of pain and the use of analgesics in 6 hours after surgery, and the same hours the next day and two days after surgery will be measured. Finally, the collected data will be analyzed and compared

Category

Rehabilitation

2**Description**

Control group :Control group: 400 cc of water is given to the patient 2 clocks before the operation, if desired. Water was given with aspartame sugar, which is a sweet solution and has zero calories. After that, the operation of the variables is checked and completed

Category

Rehabilitation

Recruitment centers**1****Recruitment center****Name of recruitment center**

Emam ali hospital

Full name of responsible person

Mehdi tavalae

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Karaj University of Medical Sciences

Full name of responsible person

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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

Karaj 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**

Karaj University of Medical Sciences

Full name of responsible person

Mehdi tavalae

Position

Associtat professor

Latest degree

Specialist

Other areas of specialty/work

General Surgery

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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

Clinical information on the effects of loading.
Carbohydrates on reducing postoperative complications
will be fully shared and laboratory and demographic data
will be shared

When the data will become available and for how long

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To whom data/document is available

Universities and scientific authorities of the iran

Under which criteria data/document could be used

Scientific

From where data/document is obtainable

Alborz University of Medical Sciences Research Assistant
Karaj. Taleghani Square Research Deputy Postal Code
3183966987 Phone 02634287335

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

Competent and enthusiastic researchers can document
data after publication Work of the responsible author by
providing academic information and self-identification
.To receive

Comments