

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

18 Jun 2026

### Investigation the Effect of preoperation oral and Infusion Riched Carbohydrate Diet on Postoperative Nausea, Vomiting and Quality of Recovery in Laparoscopic Cholecystectomy Surgery

#### Protocol summary

##### Study aim

Investigation the effect of preoperation oral and infusion riched carbohydrate diet on postoperative nausea, vomiting and quality of recovery in laparoscopic cholecystectomy surgery

##### Design

clinical single blind trial with control groupe divided into 3 parallel groups by an independent researcher according to the computer number generator.

##### Settings and conduct

Selection of laparoscopic cholecystectomy cases is performed in general surgery department of Rasoul Akram Hospital. In this single blind study, Participants remain unaware of a particular intervention group after obtaining informed consent and general introduction of study groups. Method: \*Perception of Last meal 8h and prevention of use of non-carbohydrate oral liquids 4h before surgery. \*The same condition of laparoscopic surgery. \*Check of BS 2h before surgery. \*Perception of Acetaminophen 15 mg/kg, TID and Plasil ampulla 10 mg altimately TID if needed. \*Check of BS in recovery room, also in first day after operation at 8:00 AM. \*Recording the patient desire to eat, pain severity, N/V score by VAS in 1, 6 and 24h after operation. \*Completion the QOR questionire at first 24h after surgery.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Elective laparoscopic cholecystectomy for cholelithiasis; Informed consent of patient, Exclusion criteria: Acute cholecystitis and Urgent surgery; Patients with open cholecystectomy surgery; Diabetes mellitus; Hepatic and Renal failure; Chronic inflammatory bowel disease; Acute recent infectoion; Patient under corticosteroid therapy or Anabolic and Catabolic drugs; Stomach empeting disorders; Gastroesophageal reflux disease

##### Intervention groups

Group 1: Infusion of 250 ml dextrose 10% Group 2: 200

ml oral carbohydrate solution(25 gr dextrose) Group 3: control group with normal diet and no perception glucose

##### Main outcome variables

nausea and vomiting and quality of recovery after surgery

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2017090231324N3**

Registration date: **2017-11-08, 1396/08/17**

Registration timing: **prospective**

Last update: **2019-01-05, 1397/10/15**

Update count: **1**

##### Registration date

2017-11-08, 1396/08/17

##### Registrant information

##### Name

Seyed Hamzeh Mousavie

##### Name of organization / entity

Iran University Of Medical Science

##### Country

Iran (Islamic Republic of)

##### Phone

+98 912 296 7445

##### Email address

mousavie.sh@iums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice Chancellor of Research, IRAN University of Medical Sciences

##### Expected recruitment start date

2018-01-21, 1396/11/01  
**Expected recruitment end date**  
2018-09-23, 1397/07/01  
**Actual recruitment start date**  
2018-02-04, 1396/11/15  
**Actual recruitment end date**  
2018-10-12, 1397/07/20  
**Trial completion date**  
2018-10-12, 1397/07/20

#### Scientific title

Investigation the Effect of preoperation oral and Infusion Riched Carbohydrate Diet on Postoperative Nausea, Vomiting and Quality of Recovery in Laparoscopic Cholecystectomy Surgery

#### Public title

Investigation the Effect of Preoperation Oral and Infusion Riched Carbohydrate Diet on Postoperative Nausea, Vomiting and Quality of Recovery in Laparoscopic Surgery of Gallbladder Removal

#### Purpose

Supportive

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

Elective Laparoscopic cholecystectomy for Cholelithiasis  
Informed consent of patient

##### Exclusion criteria:

Acute cholecystitis and Urgent surgery Patients with open cholecystectomy surgery Diabetes mellitus Hepatic and Renal failure Chronic inflammatory bowel disease Acute recent infectoion Patient under corticosteroid therapy or Anabolic and Catabolic drugs Stomach empeting disorders Gastroesophageal reflux disease

#### Age

From **18 years** old

#### Gender

Both

#### Phase

3

#### Groups that have been masked

- Outcome assessor

#### Sample size

Target sample size: **78**

Actual sample size reached: **78**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

Participants remain unaware of a particular intervention group after obtaining informed consent and general introduction of study groups.

#### Blinding (investigator's opinion)

Single blinded

#### Blinding description

The researcher who evaluates the results of intervention in patients after intervention is unaware of intervention type.

#### Placebo

Used

#### Assignment

Parallel

#### Other design features

#### Secondary Ids

empty

#### Ethics committees

##### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Iran University of Medical Sciences

##### Street address

Near Milad tower, Hemmat Highway

##### City

Tehran

##### Province

Tehran

##### Postal code

1111111111

#### Approval date

2017-08-12, 1396/05/21

#### Ethics committee reference number

IR.IUMS.FMD.REC1395.9021216158

#### Health conditions studied

##### 1

#### Description of health condition studied

Cholecystitis

#### ICD-10 code

#### ICD-10 code description

#### Primary outcomes

##### 1

#### Description

nausea and vomiting score

#### Timepoint

1, 6 and 24 hour after surgery

#### Method of measurement

Visual Analogue Scale

##### 2

#### Description

quality of recovery Score

#### Timepoint

1, 6 and 24 hour after surgery

#### Method of measurement

Quality Of Recovery Questionnaire

#### Secondary outcomes

##### 1

#### Description

duration of hospitalization

## **Timepoint**

duration of hospitalization after surgery

## **Method of measurement**

patient hospitalization file

## **2**

### **Description**

blood sugar

### **Timepoint**

2 hours before surgery, immediately after surgery and first day after operation at 8:00

### **Method of measurement**

laboratory kit

## **3**

### **Description**

duration of recovery

### **Timepoint**

duration of patient recovery time

### **Method of measurement**

interview and inspection

## **4**

### **Description**

pain score after surgery

### **Timepoint**

severity of pain at 1, 6 and 24 hours after surgery

### **Method of measurement**

Visual Analogue Scale

## **5**

### **Description**

status of starving

### **Timepoint**

the time of patient desire to eat

### **Method of measurement**

interview

## **6**

### **Description**

duration of anesthesia

### **Timepoint**

duration of patient anesthesia after surgery

### **Method of measurement**

nursery records and inspection

## **7**

### **Description**

Surgery Complications

### **Timepoint**

Any complication after surgery such as: Bleeding, Ulcer infection, Ileus, Pneumonia ...

### **Method of measurement**

Patient File

## **8**

### **Description**

the amount of analgesic drug administered

### **Timepoint**

after surgery

### **Method of measurement**

patient file

## **9**

### **Description**

the amount of anti-nausea drug administered

### **Timepoint**

after surgery

### **Method of measurement**

patient file

## **10**

### **Description**

past medical history (disease history)

### **Timepoint**

any disease during surgery

### **Method of measurement**

interview

## **Intervention groups**

### **1**

#### **Description**

group1: 250 ml dextrose 10% infusion 2 hours before surgery

#### **Category**

Treatment - Other

### **2**

#### **Description**

group2: 200 ml oral carbohydrate solution (includes 25 gram of dextrose 10%), 2 hours before surgery

#### **Category**

Treatment - Other

### **3**

#### **Description**

group3: control group with normal diet and no perception of glucose

#### **Category**

Treatment - Other

## **Recruitment centers**

### **1**

#### **Recruitment center**

##### **Name of recruitment center**

Rasoul Akram Hospital

##### **Full name of responsible person**

Parisa Hosseinpour

##### **Street address**

Rasool Akram Hospital, Niayesh street, Satarkhan street

**City**

Tehran

**Province**

Tehran

**Postal code**

1111111111

**Phone**

+98 21 8670 3359

**Email**

Dr.parisahosseinpour@gmail.com

**2**

**Recruitment center**

**Name of recruitment center**

Rasoul akram hospital

**Full name of responsible person**

parisahosseinpour

**Street address**

sattarkhan street, niayesh street

**City**

tehran

**Province**

Tehran

**Postal code**

1111111111

**Phone**

+98 21 6666 6666

**Email**

dr.persia1990@gmail.com

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Vice Chancellor Of Research, Iran University of Medical Science

**Full name of responsible person**

Parisa Hosseinpour

**Street address**

Near Milad tower, Hemmat highway

**City**

Tehtan

**Province**

Tehran

**Postal code**

۱۴۴۹۶۱۴۵۳۵

**Phone**

+98 21 86701

**Email**

Dr.parisahosseinpour@gmail.com

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Vice Chancellor Of Research, Iran University of Medical

Science

**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

**2**

**Sponsor**

**Name of organization / entity**

Vice Chancellor Of Research, Iran University of Medical Science

**Full name of responsible person**

dr kazem malakouti

**Street address**

Near Milad tower, Hemmat highway

**City**

tehran

**Province**

Tehran

**Postal code**

۱۴۴۹۶۱۴۵۳۵

**Phone**

+98 21 86701

**Email**

PR@iums.ac.ir

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**Grant code / Reference number**

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

Yes

**Title of funding source**

Vice Chancellor Of Research, Iran University of Medical Science

**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**

Iran University of Medical Sciences

**Full name of responsible person**

Parisa Hosseinpour

**Position**

Intern

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Others

**Street address**

Rasool Akram Hospital, Niayesh Street, Satarkhan Street

**City**

Tehran

**Province**

Tehran

**Postal code**

1111111111

**Phone**

+98 21 8670 3359

**Fax****Email**

Dr.parisahosseinpour@gmail.com

**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Parisa Hosseinpour

**Position**

intern

**Latest degree**

Medical doctor

**Other areas of specialty/work**

General Practitioner

**Street address**

Rasool Akram Hospital, Niayesh Street, Satarkhan Street

**City**

Tehran

**Province**

Tehran

**Postal code**

1111111111

**Phone**

+98 21 8670 3359

**Fax****Email**

Dr.parisahosseinpour@gahoo.com

**Web page address****Person responsible for updating data****Contact****Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Parisa Hosseinpour

**Position**

intern

**Latest degree**

Medical doctor

**Other areas of specialty/work**

General Practitioner

**Street address**

Rasool Akram Hospital, Niayesh Street, Satarkhan Street

**City**

Tehran

**Province**

Tehran

**Postal code**

1111111111

**Phone**

+98 21 8670 3359

**Fax****Email**

Dr.parissahosseinpour@gmail.com

**Web page address****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