Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Investigation the Effect of preoperation oral and Infusion Riched Carbohydrate Diet on Postoperative Nausea, Vomiting and Quality of Recovery in Laparascopic 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 laparascopic 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 laparascopic 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-carbohydarte oral liquids 4h before surgery.*The same condition of laparascopic 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 questionnire at first 24h after surgery.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Elective laparascopic 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

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source
Vice Chanceller 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 Laparascopic 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 Laparascopic 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 houre after surgery

Method of measurement

Visual Analogue Scale

2

Description

quality of recovery Score

Timepoint

1, 6 and 24 houre 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 houre 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 pateint recovery time
Method of measurement
interview and inspection

4

Description
pain score after surgery
Timepoint
severity of pain at 1, 6 and 24 hour after surgery
Method of measurement
Visual Analogue Scale

5

Description
strat 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, Pnomonia ...
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
patent file

10

Description
past medical history(diseae 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 solusion (includes 25 gram of dextrose 10%), 2 horse before surgery
Category
Treatment - Other

3

Description
group 3: 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

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2

Recruitment center

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice Chancellor Of Research, Iran University of Medical Science

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
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
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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
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
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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