

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of the Effects of Two Methods of Liberal and Restericted Fluid Therapy on Renal Function Indices in Gastric Bypass by Laparoscopic

Protocol summary

Registration timing: **registered_while_recruiting**

Study aim

Comparison of the Effects of Two Methods of Liberal and Restericted Fluid Therapy on Renal Function Indices in Gastric Bypass by Laparoscopic

Last update: **2019-08-07, 1398/05/16**

Update count: **0**

Registration date

2019-08-07, 1398/05/16

Design

Single central, randomized, Single-blind, Phase 2 clinical trials. Seventy-seven candidates for gastric bypass surgery were assigned to a similar number in two groups under pre-operative restructured fluid therapy and pre-operative liberal fluid therapy.

Registrant information

Name

Mahzad Alimian

Name of organization / entity

Iran University of Medical Science

Country

Iran (Islamic Republic of)

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Email address

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Settings and conduct

Patients undergoing laparoscopic gastric Bypass surgery in Rasoul-e-Akram Hospital will be randomly assigned to pre-operative restructured fluid therapy and undergo pre-operative liberal fluid therapy. So that the patient does not know the patient's assigned group.

Recruitment status

Recruitment complete

Funding source

Participants/Inclusion and exclusion criteria

Inclusion criteria for study include: All patients undergoing gastric bypass surgery by Laparoscopic.
Exclusion criteria for study include: age below 18 years, history of preoperative renal dysfunction, history of cardiovascular and pulmonary disease, and pregnancy.

Expected recruitment start date

2019-06-22, 1398/04/01

Expected recruitment end date

2019-08-23, 1398/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Intervention groups

The first intervention group was placed under preoperative restructured fluid therapy and the second intervention group was placed under preoperative free-fluid therapy.

Scientific title

Comparison of the Effects of Two Methods of Liberal and Restericted Fluid Therapy on Renal Function Indices in Gastric Bypass by Laparoscopic

Main outcome variables

The main outcome is the serum BUN.

Public title

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170109031852N3**

Registration date: **2019-08-07, 1398/05/16**

Effects of Liberal and Restericted Fluid Therapy on Renal Function

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Inclusion criteria for study include: All patients undergoing gastric bypass surgery by Laparoscopic.
Exclusion criteria:
Exclusion criteria for study include: age below 18 years, history of preoperative renal dysfunction, history of cardiovascular and pulmonary disease, and pregnancy.

Age
From **18 years** old

Gender
Both

Phase
2

Groups that have been masked

- Participant

Sample size
Target sample size: **72**

Randomization (investigator's opinion)
Randomized

Randomization description
A simple random method will be used using a random number table.

Blinding (investigator's opinion)
Single blinded

Blinding description
Participants in the study were not informed about the prescribed treatment group.

Placebo
Not 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
Iran University of Medical Sciences, next to Milad Tower, Hemat Highway
City
Tehran
Province
Tehran
Postal code
۱۳۴۹۶۱۴۵۳۵
Approval date

2018-02-26, 1396/12/07

Ethics committee reference number
IR.IUMS.FMD.REC.1396.9411174020

Health conditions studied

1

Description of health condition studied
Gastric Bypass
ICD-10 code
Y83.2
ICD-10 code description
Surgical operation with anastomosis, bypass or graft

Primary outcomes

1

Description
Serum BUN
Timepoint
Before and 24 hours after surgery
Method of measurement
Obtaining venous blood samples and laboratory techniques

Secondary outcomes
empty

Intervention groups

1

Description
Intervention group 1: Under the restructured fluid treatment before surgery.
Category
Treatment - Drugs

2

Description
Intervention group 2: Under the liberal fluid treatment before surgery.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Rasoul-e-Akram Hospital
Full name of responsible person
Mahzad Alimian
Street address
Rasool Akram Hospital, Maziar Mansouri Ave, Sattarkhan Street
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Seyed Kazem Malakouti
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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

Iran 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
Iran University of Medical Sciences
Full name of responsible person
Mahzad Alimian
Position
Associate Professor
Latest degree

Specialist
Other areas of specialty/work
Anesthesiology
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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

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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

The whole potential data is unpublished after being unidentifiable.

When the data will become available and for how long

Start the access period 6 months after printing the results.

To whom data/document is available

Researchers working in academic and industrial institutions.

Under which criteria data/document could be used

It can be used to carry out research work.

From where data/document is obtainable

Dr. Mahzad Alimian, Faculty of Medicine, Iran University of Medical Sciences.

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

Sending request is available.

Comments