

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

comparative study of the mean urinary level of oxalate after Roux-n-Y gastric bypass, omega loop gastric bypass and sleeve gastrectomy in patients referred to Alzahra and Kashani hospital

Protocol summary

Study aim

1- Determination and comparison of the average level of urinary oxalate according to kind of surgery 2- Determination and comparison of the average level of urinary oxalate according to the sex 3- Determination and comparison of the average level of urinary oxalate according to the age 4- Determination and comparison of the average level of urinary oxalate according to patients BMI before surgery

Design

In this research, 105 eligible obese patients will be chosen from Alzahra hospital and Kashani Hospital with convenience sampling. Then, patients will be divided into 3 groups randomly.

Settings and conduct

In this research, obese patients between 18-60 years old referring to Isfahan Alzahra hospital and Kashani Hospital and undergo Roux-en-Y gastric bypass, Omega-loop gastric bypass and sleeve gastrectomy surgery were chosen. Then urine oxalate will be measured and compared to other groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: consent to participate; need to bariatric surgery; age between 18-60 years old. Exclusion criteria: History of the diseases that may be associated with hyperoxaluria such as Diabetes mellitus, IBD, primary hyperoxaluria and... based on patient history and cases; taking Hydrochlorothiazide medications; taking drugs that affect oxalate or calcium oxalate supersaturation; Lack of cooperation; pregnancy after surgery.

Intervention groups

Each group will undergo one surgical procedure: Roux-en-Y gastric bypass, Omega loop gastric bypass and sleeve gastrectomy

Main outcome variables

Determination and comparison of the average level of urinary oxalate after 3 surgical procedures: Roux-en-Y

gastric bypass, Omega loop gastric bypass and sleeve gastrectomy.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171118037525N1**

Registration date: **2017-12-01, 1396/09/10**

Registration timing: **registered_while_recruiting**

Last update: **2017-12-01, 1396/09/10**

Update count: **0**

Registration date

2017-12-01, 1396/09/10

Registrant information

Name

Flora Mazaheri

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 36246171

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Isfahan University of Medical Sciences

Expected recruitment start date

2017-02-19, 1395/12/01

Expected recruitment end date

2018-03-20, 1396/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

comparative study of the mean urinary level of oxalate after Roux-n-Y gastric bypass, omega loop gastric bypass and sleeve gastrectomy in patients referred to Alzahra and Kashani hospital

Public title

Determination and comparison of urine oxalate after different bariatric surgery

Purpose

Diagnostic

Inclusion/Exclusion criteria**Inclusion criteria:**

Informed consent to participate in research need to bariatric surgery based on ASMBS(American society for metabolic and bariatric surgery) age between 18-60 years old

Exclusion criteria:

History of the diseases that may be associated with hyperoxaluria such as Diabetes mellitus, IBD, primary hyperoxaluria, hyperparathyroidism, chronic diarrhea, short bowel syndrome, liver disease, thyroid disease, immunological diseases, cancers, chronic renal failure, urinary tract infections, pregnancy and lactation based on patient history and cases taking Hydrochlorothiazide medications taking drugs that affect oxalate or calcium oxalate supersaturation Lack of cooperation pregnancy after surgery

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **105**

Randomization (investigator's opinion)

Randomized

Randomization description

Convenience sampling will be done and then samples will be separated to groups randomly via computer software

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Isfahan University of Medical Sciences

Street address

Isfahan University of Medical Sciences, Hezarjarib avenue

City

Isfahan

Province

Isfahan

Postal code

6939177143

Approval date

2017-07-19, 1396/04/28

Ethics committee reference number

IR.MUI.REC.1396.3.502

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

Obesity

ICD-10 code

E66

ICD-10 code description

Obesity

Primary outcomes**1****Description**

24 hour urine oxalate

Timepoint

Before the intervention, 1 month after the intervention, 4 months after the intervention and 7 months after the intervention

Method of measurement

Enzymatic method

Secondary outcomes

empty

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

Intervention group: Patients undergo Roux-en-Y gastric bypass surgery

Category

Treatment - Surgery

2

Description

Intervention group: Patients undergo omega loop gastric bypass surgery

Category

Treatment - Surgery

3

Description

Intervention group: Patients undergo sleeve gastrectomy surgery

Category

Treatment - Surgery

4

Description

Control group: With no intervention

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Ayatollah Kashani Hospital

Full name of responsible person

Zeinab Balouchi

Street address

Ayatollah Kashani Hospital, Ayatollah Kashani st.

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2

Recruitment center

Name of recruitment center

Alzahra Hospital

Full name of responsible person

Peyman Soleimani

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Alzahra Hospital, Soffeh St., Isfahan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Isfahan University of Medical Sciences

Full name of responsible person

Ahmad Movahedian Attar

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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

Isfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Masoud Sayadi

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

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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