

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jun 2026

Gastric mapping for intestinal metaplasia and dysplasia in morbid obese patients candidate for bariatric surgery

Protocol summary

Summary

Determining gastric mapping for dysplasia and intestinal metaplasia in obese who are at increased risk of gastric cancer due to their obesity can be of value for determining places with higher probability of such pathologies and doing biopsy from these locations during endoscopy. Such mapping can also be helpful in better follow up of these patients for early diagnosis of cancerous lesions. This quasi-experimental study, will be done on 174 obese cases candidate for bariatric surgery who have tendency for doing gastric endoscopy with biopsy and aged between 18 and 70 years old. A general practitioner will evaluate demographic variables and determine height and weight. All patients who sign an informed consent form will be endoscopically evaluated and gastric biopsy will be done. CBC, platelet, ESR, CRP, FBS, TG, Chol, HDL, and LDL will also be determined after taking blood sample. Endoscopy will be done before surgery under sedation with propofol and after confirming by a cardiologist. Our outcome variables are: H. pylori infection, mucosal atrophy, chronic gastritis, reactive atypia of glandular epithelium, intestinal metaplasia, dysplasia, CBC, platelet, ESR, CRP, FBS, TG, Chol, HDL, and LDL.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201305204811N3**
Registration date: **2015-05-23, 1394/03/02**
Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2015-05-23, 1394/03/02

Registrant information

Name

Ali Kabir

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Iran University of Medical Sciences

Expected recruitment start date

2015-06-22, 1394/04/01

Expected recruitment end date

2016-06-21, 1395/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Gastric mapping for intestinal metaplasia and dysplasia in morbid obese patients candidate for bariatric surgery

Public title

Determining intestinal metaplasia and dysplasia in obese patients candidate for surgery

Purpose

Diagnostic

Inclusion/Exclusion criteria

Inclusion criteria: Morbid obese patients (BMI > 35 kg/m²), aged between 18 and 70 years old who are not involved in any other interventional study, have tendency for doing upper endoscopy and gastric biopsy.

Exclusion criteria: Cases with any severe diseases of kidney and heart and any other end stage diseases.

Age

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

Gender

Both

Phase

0

Groups that have been masked

No information

Sample size

Target sample size: **174**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

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

5th Floor, Central Building of Iran University of Medical Sciences, Hemmat Expway, between Sheikh fazlollah and Chamran Expway

City

Tehran

Postal code

Approval date

2015-05-11, 1394/02/21

Ethics committee reference number

94-01-14-25669-111701

Health conditions studied

1

Description of health condition studied

Obesity and sleep apnea

ICD-10 code

E66.2

ICD-10 code description

Extreme obesity with alveolar hypoventilation

2

Description of health condition studied

Obesity

ICD-10 code

E66.0

ICD-10 code description

Obesity due to excess calories

3

Description of health condition studied

all types of obesity

ICD-10 code

E66.9

ICD-10 code description

Simple obesity NOS

4

Description of health condition studied

Morbid obesity

ICD-10 code

E66.8

ICD-10 code description

Morbid obesity

Primary outcomes

1

Description

gastric dysplasia

Timepoint

At the beginning of study

Method of measurement

gastric biopsy

2

Description

mucosal atrophy

Timepoint

At the beginning of study

Method of measurement

gastric biopsy

3

Description

H. pylori infection

Timepoint

At the beginning of study

Method of measurement

gastric biopsy

4

Description

gastric metaplasia

Timepoint

At the beginning of study

Method of measurement

gastric biopsy

5

Description

chronic gastritis

Timepoint

At the beginning of study

Method of measurement

gastric biopsy

6

Description

reactive atypia of glandular epithelium

Timepoint

At the beginning of study

Method of measurement

gastric biopsy

Secondary outcomes

1

Description

FBS

Timepoint

at the beginning of study

Method of measurement

ELISA

2

Description

TG

Timepoint

at the beginning of study

Method of measurement

ELISA

3

Description

Total Cholesterol, LDL, HDL

Timepoint

at the beginning of study

Method of measurement

ELISA

4

Description

CRP, ESR

Timepoint

at the beginning of study

Method of measurement

ELISA

Intervention groups

1

Description

All patients who sign an informed consent form will be endoscopically evaluated and gastric biopsy will be done. CBC, platelet, ESR, CRP, FBS, TG, Chol, HDL, and LDL will also be determined after taking blood sample. Endoscopy will be done before surgery under sedation with propofol and after confirming by a cardiologist.

Category

Diagnosis

Recruitment centers

1

Recruitment center

Name of recruitment center

Minimally invasive surgery research center and Endoscopy ward of the Hazrat Rasoul-e- Akram Hospital

Full name of responsible person

Dr Abdolreza Pazouki

Street address

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Iran University of Medical Sciences

Full name of responsible person

Dr Seyed Ali Javad Mousavi

Street address

Room #503, %th floor, Central building of Iran University of Medical Sciences, between Chamran and Hemmat Expways, Hemmat Expway

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research, Iran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Ali Kabir

Position

MD, PhD of Epidemiology

Other areas of specialty/work**Street address**

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty