

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jun 2026

Comparison between Roux en Y gastrojejunostomy and Billroth II with Braun anastomosis in partial gastrectomy patients

Protocol summary

Study aim

The aim of this study was to compare gastrointestinal function & complication after gastrectomy in Billroth2 with Braun anastomosis & Roux en Y gastrojejunostomy reconstructions.

Design

Two arm parallel group randomized clinical trial with 80 patients in two groups. Randomization method is randomized block randomization .

Settings and conduct

The study is conducted in Be'sat hospital & Taleghani hospital in Tehran. This is single blinded trial and the patients have no information about gastric reconstruction technique.

Participants/Inclusion and exclusion criteria

Patients diagnosed with gastric cancer or gastric ulcer who are candidate for partial gastrectomy. Exclusion criteria: ASA score more than 3, pregnancy, synchronous other malignancy and uncontrolled disease.

Intervention groups

Gastrectomy patients assigned to two groups, first with Billroth 2 with Braun anastomosis as gastric reconstruction technique and the other with Roux en Y gastrojejunostomy.

Main outcome variables

In patients follow up, we assess reflux, dumping syndrome, obstruction and delayed emptying and admission. If the patients have any symptoms, endoscopic evaluation will be done for gastritis, esophagitis, and anastomosis site stenosis.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130706013875N3**

Registration date: **2020-05-05, 1399/02/16**

Registration timing: **registered_while_recruiting**

Last update: **2020-05-05, 1399/02/16**

Update count: **0**

Registration date

2020-05-05, 1399/02/16

Registrant information

Name

Farhad Fathi

Name of organization / entity

Shahid Beheshti University of Medical Sciences

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Iran (Islamic Republic of)

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ffathi@student.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-07-30, 1398/05/08

Expected recruitment end date

2020-07-29, 1399/05/08

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison between Roux en Y gastrojejunostomy and Billroth II with Braun anastomosis in partial gastrectomy patients

Public title

Comparison between Roux en Y gastrojejunostomy and Billroth II with Braun anastomosis

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Patients diagnosed with gastric cancer or gastric ulcer who are candidate for partial gastrectomy

Exclusion criteria:

Patients who are or become pregnant
Patients with uncontrolled disease
Patients with synchronous other malignancy
Patients with American Society Anesthesiology Score more than 3

Age

From **18 years** old to **75 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization: Individuals are randomly divided into two groups based on randomized block randomization method. Randomized blocks are used for this purpose. A random sample based on this method from Sealedenvelope.com has been extracted.

Blinding (investigator's opinion)

Single blinded

Blinding description

None of the patients are aware of the technique of their surgery, but the surgeon and the researcher are aware of the type of technique for each patient.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

AJA University of Medical Sciences

Street address

AJA universitu of Medical Sciences, ,Etemadzadeh st,West Fatemi Ave.Amirabad town

City

Tehran

Province

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Postal code

IR.AJAUMS.REC.1398.0

Approval date

2019-07-30, 1398/05/08

Ethics committee reference number

IR.AJAUMS.REC.1398.092

Health conditions studied

1

Description of health condition studied

gastric cancer

ICD-10 code

C16

ICD-10 code description

Malignant neoplasm of stomach

2

Description of health condition studied

Gastric ulcer

ICD-10 code

K25

ICD-10 code description

Gastric ulcer

Primary outcomes

1

Description

Gastroesophageal Reflux

Timepoint

3 months after surgery

Method of measurement

GerdQ questionnaire

2

Description

Dumping syndrome

Timepoint

3 months after surgery

Method of measurement

Medical history taking and examination

3

Description

obstruction and delayed emptying

Timepoint

3 months after surgery

Method of measurement

Medical history taking and examination

4

Description

Gastritis

Timepoint

3 months after surgery

Method of measurement

Endoscopy

5

Description

esophagitis

Timepoint

3 months after surgery

Method of measurement

Endoscopy

6

Description

Anastomosis site stenosis

Timepoint

3 months after surgery

Method of measurement

Endoscopy

Secondary outcomes

empty

Intervention groups

1

Description

Billroth II with Braun anastomosis group: After gastrectomy, reconstruction will be performed with Billroth 2 and Braun anastomosis.

Category

Treatment - Surgery

2

Description

Roux en Y gastrojejunostomy group: After gastrectomy, reconstruction will be performed with Roux en Y gastrojejunostomy procedure.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Be'sat Hospital

Full name of responsible person

Farhad Fathi

Street address

Be'sat Hospital, Hejrat st, Basij highway, Tehran

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2

Recruitment center

Name of recruitment center

Taleghani Hospital

Full name of responsible person

Farhad Fathi

Street address

Taleghani Educational Hospital, Aarabi St., Velenjak Region, Chamran High Way, Tehran, Iran

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taleghanihospital@sbm.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Artesh University of Medical Sciences

Full name of responsible person

Dr Saeed Soleiman Meigooni

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dr.saeedmeigooni@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Artesh 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

Artesh University of Medical Sciences

Full name of responsible person

Farhad Fathi

Position

Researcher

Latest degree

Specialist

Other areas of specialty/work

General Surgery

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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