Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Oct 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 gastrojejeunostomy 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 gastrojejenustomy.

Main outcome variables
In patients follow up, we assess reflux, dumping syndrome, obstruction and delayed emptying and addmission. 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 Sciencces

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Iran (Islamic Republic of)

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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

Tehran

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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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Artesh University of Medical Sciences
Full name of responsible person
Dr Saeed Soleiman Meigooni
Street address
AJA University of Medical Sciences, Etemadzadeh St, Fatemi Ave. Tehran
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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