

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

Effects of adding Braun jejunostomy to standard Whipple procedure on reduction of afferent loop syndrome- A Randomized control clinical trial .

Protocol summary

Summary

30 patients(18-75Y/O) of pancreatic head, duodenal or common bile duct tumor which need Whipple procedure which are operable according to the preoperative imaging studies will be recruited for this study and will be randomized by Randlist software into 2 equal groups. The control group will be undergone the standard Whipple procedure. In the intervention group a Braun jejunostomy will be added to the standard procedure. Those who are inoperable according to intraoperative findings or those who die during the operation will be excluded from the study. The following variables will be collected by a questionnaire to compare between the two groups: age, gender, body mass index, time from the first symptoms till the operation, cause of the disease (pancreatic head, or duodenal, or common bile duct tumor), duration of the operation, intraoperative bleeding, total volume of intraoperative blood product transfusion, pre- and postoperative lab data (WBC, Hb, ALT, AST, Total and direct bilirubin) in days 1, 3, 5, 7 and 14, volume of nasogastric tube evacuations for 48 hours after the operation, daily number of vomitings after extraction of nasogastric tubes, postoperative complications including death and its cause, pancreatic anastomosis leakage, gastric anastomosis leakage, biliary anastomosis leakage, postoperative bleeding which needs another operation, postoperative gastrointestinal bleeding which needs repeat operation, afferent loop syndrome, delayed gastric emptying, surgical site infection, pulmonary infection, confirmed deep vein thrombosis. Follow-up of the patients will be continued till 1 month after the operation or in-hospital death.

General information

Acronym

Braun jejunostomy

IRCT registration information

IRCT registration number: **IRCT2014020316473N1**

Registration date: **2014-02-26, 1392/12/07**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-02-26, 1392/12/07

Registrant information

Name

Farzad Kakaei

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 1334 1317

Email address

fkakaei@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Tabriz University of Medical Sciences

Expected recruitment start date

2013-05-22, 1392/03/01

Expected recruitment end date

2014-03-20, 1392/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of adding Braun jejunojejunostomy to standard Whipple procedure on reduction of afferent loop syndrome- A Randomized control clinical trial .

Public title

Effects of adding Braun jejunojejunostomy to standard Whipple procedure on reduction of afferent loop syndrome- A Randomized control clinical trial .

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age between 18-75 years; operability according to the preoperative imaging studies (no invasion to portal vein, superior mesenteric artery or superior mesenteric vein, no distant metastasis, no invasion to adjacent organs); presence of pancreatic head, or duodenal, or common bile duct tumor which needs Whipple procedure Exclusion criteria: age over 75 or less than 18; death during the operation; inoperability according to any intraoperative findings

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description**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**

Tabriz University of Medical Sciences

Street address

Golgasht Street

City

Tabriz

Postal code**Approval date**

2013-09-30, 1392/07/08

Ethics committee reference number

92106

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

Malignant neoplasm: Head of pancreas

ICD-10 code

C25.0

ICD-10 code description

Malignant neoplasm: Head of pancreas

2**Description of health condition studied**

Malignant neoplasm: Ampulla of Vater

ICD-10 code

C24.1

ICD-10 code description

Malignant neoplasm: Ampulla of Vater

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

afferent loop syndrome

Timepoint

during the hospital stay after the third day after the operation

Method of measurement

Questionnaire (sudden bulky bile stained vomitus without any relation to eating)

Secondary outcomes**1****Description**

postoperative death

Timepoint

during the total hospital stay

Method of measurement

questionnaire

2**Description**

pancreatic anastomosis leakage

Timepoint

daily till discharge

Method of measurement

questionnaire (high amylase drainage from drains)

3**Description**

gastric anastomosis leakage

Timepoint

daily till discharge

Method of measurement

questionnaire (low pH drainage from drains)

4

Description

biliary anastomosis leakage

Timepoint

daily till discharge

Method of measurement

questionnaire (high bilirubin drainage from drains)

5

Description

postoperative bleeding which needs another operation

Timepoint

daily till discharge

Method of measurement

questionnaire

6

Description

postoperative gastrointestinal bleeding which needs repeat operation

Timepoint

daily till discharge

Method of measurement

questionnaire

7

Description

surgical site infection

Timepoint

daily till discharge

Method of measurement

questionnaire

Intervention groups

1

Description

The control group will be undergone the standard Whipple procedure. Two layer ductojejunostomy will be used for pancreaticojejunostomy anastomosis. Choledochojejunostomy will be done 5-10 centimeter distal to the pancreaticojejunostomy in 1 layer by 4-0 PDS separate sutures and the gastrojejunostomy will be done in ante colic manner 30-45 centimeter distal to the previous anastomosis. At the end of the procedure, two corrugate drain will be inserted in the liver bed and pancreatic bed in the right and left side respectively.

Category

Treatment - Surgery

2

Description

The intervention group will be undergone the standard Whipple procedure plus Braun jejunoejunostomy. Two layer ductojejunostomy will be used for

pancreaticojejunostomy anastomosis. Choledochojejunostomy will be done 5-10 centimeter distal to the pancreaticojejunostomy in 1 layer by 4-0 PDS separate sutures and the gastrojejunostomy will be done in ante colic manner 30-45 centimeter distal to the previous anastomosis. Braun jejunoejunostomy will be done in 2 layer by PDS 2-0 in standard manner, the distance between the anastomosis and choledochojejunostomy anastomosis will be near 30 centimeter and the distal loop will be near 40 centimeter. At the end of the procedure, two corrugate drain will be inserted in the liver bed and pancreatic bed in the right and left side respectively.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

surgery unit of Tabriz Imam Reza hospital

Full name of responsible person

Dr Farzad Kakaei

Street address

Golgasht Street

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Mohammad Reza Rashidi

Street address

Golgasht Street

City

Tabriz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Farzad Kakaei

Position

associate professor of surgery

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

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Person responsible for updating data

Contact

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Full name of responsible person

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Position

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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