

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of pancreaticojejunostomy by mucosectomy technique and its routine method in whipple surgery

Protocol summary

Summary

The aim of this study was to assess improved outcomes in patients with pancreatic head tumor who underwent pancreaticojejunostomy by muscetomy technique during whipple procedure. The patients will consist of subjects with pancreatic head tumor which are resectable by whipple procedure. A total of 20 patients will be studied during one year from April 2013. The patients will randomly be divided into two groups. In both groups, whipple procedure will be conducted for resection of head of the pancreas. In mucosectomy group (Group 1), anastomosis of pancreaticojejunostomy will be done by musectomy technique, while in the routine group (Group 2) routine anastomosis techniques will be applied. Age, sex, size of tumor and preoperative serum albumin level would be recorded for all patients. Size of pancreatic duct and fragility of pancreatic tissue will also be recorded. Leak of pancreaticojejunostomy will be assessed by development of pancreatic fistula. Postoperative admission days, NPO (nul per os) days, infectious complications, the need for blood transfusion and octreotide use will be recorded for all patients. The outcomes will be compared between two groups to evaluate possible beneficial effects of mucosectomy technique. The comparison of outcomes between two groups will be double-blind and the surgeon who evaluates patients postoperatively will not be aware of the patients' anastomosis technique.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013060113545N1**

Registration date: **2014-03-22, 1393/01/02**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-03-22, 1393/01/02

Registrant information

Name

Fariborz Rousta

Name of organization / entity

Tabriz University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Tabriz University of Medical Sciences

Expected recruitment start date

2013-05-08, 1392/02/18

Expected recruitment end date

2014-05-08, 1393/02/18

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of pancreaticojejunostomy by mucosectomy technique and its routine method in whipple surgery

Public title

Pancreaticojejunostomy by mucosectomy technique in whipple procedure

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1-Mass of head of pancreas; 2-Being candidate for whipple procedure;3- Being more than 18 years of age Exclusion criteria: Involvement of other parts of pancreas; Metastasis; Inoperable presentation; being high risk for whipple procedure

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 20

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Single 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

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Golgasht St. Research Vice Chancellor Office, Tabriz
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Tabriz

Postal code

51664

Approval date

2013-05-08, 1392/02/18

Ethics committee reference number

9224

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

Pancreatic head tumor

ICD-10 code

K86.9

ICD-10 code description

Disease of pancreas, unspecified

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

Aanastomotic leak

Timepoint

10 days after operation

Method of measurement

Physical examination, assessment of outputs of drains and assessment of presence of pancreatic fistula

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

Postoperative conditions

Timepoint

10 days after the operation

Method of measurement

Postoperative admission days, NPO days, the need for blood transfusion and octreotide use

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

The intervention of this trial would be the musectomy technique. This would be applied for intervention group (musectomy group) during pancreaticojejunostomy anastomosis. In control group, pancreaticojejunostomy anastomosis will be done by routine technique. For musectomy, 3-5 mm of mucosa of jejunum will be resected by this scalpel and then pancreaticojejunostomy anastomosis will be done between mucosa of jejunum (distal to mucosectomy) and the pancreas. Then muscular layer of distal part of jejunum (the site of mucosectomy) will be attached to the pancreatic tissue by separate sutures.

Category

Treatment - Surgery

Recruitment centers**1****Recruitment center****Name of recruitment center**

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Hemmat Maghsoudi

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Golgasht St. tabriz University of Medical Sciences

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

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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

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**

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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