

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of the effect of preoperative biliary drainage in periampullary cancer

Protocol summary

Summary

In this clinical trial study, population of patients with obstructive jaundice after Pancreas tumor or periampullary will be selected of Ahvaz Golestan hospital and Alzahra Isfahan hospital during the years 2013-2016. Patients with obstructive jaundice after surgical pancreatic tumor will be included. Patients with underlying severe lack of surgical facilities curative; therapy for this malignancy and metastatic liver need to neoadjuvant will be excluded. Drainage will be done with two method, for external percutaneous trans-hepatic bile duct by inserting a catheter or endoscopic retrograde cannulation of the bile duct, for internal put a Endoprosthesis. Both methods used today, but the benefits of biliary drainage before cancer surgery do not agreed. Patients after six months will be tested for bilirubin, liver function enzymes, albumin, amylase, lipase, blood tests of kidney function after surgery, the incidence of long-term outcomes and mortality will be studied

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016050327725N1**

Registration date: **2016-06-20, 1395/03/31**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2016-06-20, 1395/03/31

Registrant information

Name

Amin Bahreini

Name of organization / entity

Ahvaz Joundishapour University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 913 435 2718

Email address

bahreini-a@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research of Ahvaz Jundishapour University of Medical Sciences

Expected recruitment start date

2016-08-22, 1395/06/01

Expected recruitment end date

2016-10-22, 1395/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of preoperative biliary drainage in periampullary cancer

Public title

Evaluation of the effect of preoperative biliary drainage in periampullary cancer

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients with obstructive jaundice after surgical pancreatic tumor. Exclusion criteria: patients with underlying severe lack of surgical facilities curative; therapy for this malignancy and metastatic liver need to Neoadjuvant .

Age

No age limit

Gender

Both

Phase

1

Groups that have been masked

No information

Sample size

Target sample size:

Randomization (investigator's opinion)

Not 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**

Ethics committee of Ahvaz Jundishapour University of Medical Sciences

Street address

Golestan ave, Ahvaz Jundishapour University of Medical Sciences, Ahvaz, Iran

City

Ahvaz

Postal code**Approval date**

2015-05-19, 1394/02/29

Ethics committee reference number

IR.AJUMS.REC.1394.229

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

Periampulary cancer

ICD-10 code

c22

ICD-10 code description

Malignant neoplasm of liver and intrahepatic bile ducts

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

Length of stay

Timepoint

After Surgery

Method of measurement

Length of stay After Surgery

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

Mortality

Timepoint

After surgery

Method of measurement

Check the number of deceased

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

Biliary drainage Surgery in Ahvaz Golestan Hospital patients

Category

Treatment - Surgery

2**Description**

Biliary drainage Surgery in Isfahan Alzahra Hospital patients

Category

Treatment - Surgery

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

Ahvaz Golestan Hospital

Full name of responsible person

Dr Amin Bahreini

Street address

Golestan Hospital, Ahvaz, Iran

City

Ahvaz

2**Recruitment center****Name of recruitment center**

Azahra Isfahan Hospital

Full name of responsible person

Dr Esmaeil Naderi

Street address

Azahra hospital, Isfahan, Iran

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research of Ahvaz Jundishapour
University of Medical Sceincese

Full name of responsible person

Dr Nader Saki

Street address

Ahvaz Jundishapour University of Medical Sceincese,
Ahvaz, Iran

City

Ahvaz

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 of Ahvaz Jundishapour
University of Medical Sceincese

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**

Ahvaz Jondishapour University of Medical Sciences

Full name of responsible person

Amin Bahreini

Position

surgery specialist

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

Golestan hospital, Ahvaz, Iran

City

Ahvaz

Postal code**Phone**

+98 913 435 2718

Fax**Email**

bahrieni-a@ajums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Ahvaz Jundishapour University of Medical Sceinces

Full name of responsible person

Dr Esmail Naderi

Position

Surgery specialist

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

Azahra hospital, Isfahan, Iran

City

Isfahan

Postal code**Phone**

+98 916 622 8363

Fax**Email**

ab55di@gmail.com

Web page address

Person responsible for updating data

Contact**Name of organization / entity**

Ahvaz Jundishapur of Medical Sciences

Full name of responsible person

Dr Amin Bahreini

Position

Surrgy Specialist

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

Golestan hospital, Ahvaz, Iran

City

Ahvaz

Postal code**Phone**

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Fax**Email****Web page address**

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