

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 2026

comparison between primary closure and T-tube drainage after open choledochotomy

Protocol summary

Summary

The aim of this study is to assess the possibility of primary repair of common bile duct in choledocolithiasis to avoid T-tube placement and its probable complications. This study has been designed as a randomized controlled trial and will be conducted in two groups. Each group will be consisted of 15 patients. In the first group, after choledocotomy and drainage of choledocal stones, T-tube will be placed using the conventional method. In the second group, primary repair will be done instead of T-tube placement. Inclusion criteria is jaundice on physical examination or hyperbilirubinemia in the presence of gall stone disease, choledochal stones in ultrasonnography, endoscopic retrograde clangiopancreatography or magnetic resonance cholangiopancreatography, intraoperative palpation of stones in CBD. Exclusion critria is patients with acute pancreatitis or colangitis presentation, suspicious malignancy, lesser than 20 or older than 80 years old, patients with history of laparotomy, history of heart failure, renal failure, cerebrovascular accidents and myocardial infarction, obese patients with body mass index greater than 35. This study will be done during a 10-month period at the Department of General Surgery, Sina Hospital, Tabriz University of Medical Sciences. The entire patients will be assessed at 2-week, 3-week and 3-month intervals. Surgical complications including intra-abdominal collections, bile leak from drains, wound infection and remnant stone will be compared between the study groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012092410918N1**

Registration date: **2012-12-10, 1391/09/20**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-12-10, 1391/09/20

Registrant information

Name

Abdolhamid Chavoshi Khamneh

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 1334 1317

Email address

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Recruitment status

Recruitment complete

Funding source

Tabriz University of Medical Sciences

Expected recruitment start date

2012-03-20, 1391/01/01

Expected recruitment end date

2012-12-21, 1391/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

comparison between primary closure and T-tube drainage after open choledochotomy

Public title

new method in the treatment of choledochal stones

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion criteria: jaundice on physical examination or hyperbilirubinemia in the presence of gall stone disease; choledochal stones in ultrasonography; ERCP or MRCP, intraoperative palpation of stones in CBD. exclusion criteria: patients with acute pancreatitis or cholangitis presentation; suspicious malignancy; lesser than 20 or older than 80 Y/O; patients with history of laparotomy; history of heart failure; renal failure; cerebrovascular accidents and myocardial infarction; obese patients with BMI>35.

Age

From **20 years** old to **70 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

Ethics committee of Tabriz University of Medical Sciences

Street address

Gogasht Ave.-Tabriz University of Medical Sciences

City

Tabriz

Postal code

Approval date

2012-04-30, 1391/02/11

Ethics committee reference number

5/4/3442

Health conditions studied

1

Description of health condition studied

choledochal stone treatment

ICD-10 code

K80.5

ICD-10 code description

Calculus of bile duct without cholangitis or cholecystitis

Primary outcomes

1

Description

biliary leak

Timepoint

During hospital stay, 2 weeks, 1 month, 3 months after surgery

Method of measurement

milliliter

2

Description

Intra-abdominal collections

Timepoint

1 month, 3 months after surgery

Method of measurement

ultrasonography

3

Description

residual stones

Timepoint

2 weeks, 1 month, 3 months after surgery

Method of measurement

ultrasonography, T-tube colangiography

4

Description

wound infection

Timepoint

During hospital stay, 2 weeks, 1 month, 3 months after surgery

Method of measurement

suppurative secretions-Ratio

Secondary outcomes

1

Description

hospital stay

Timepoint

During admission

Method of measurement

day-calendar

2

Description

operating time

Timepoint

during admission

Method of measurement

hour

3

Description

time to removal of drain

Timepoint

during admission

Method of measurement

day-calendar

Intervention groups

1

Description

All patients undergo operation with right subcostal incision, then the vertical incision made in the CBD. The stones take out with stone forceps and saline flushing. complete clearance of CBD confirm with intraoperative colangiography. Next, in control group; T-tube of appropriate size insert into the CBD incision and CBD incision will be closed using interrupted absorbable sutures.

Category

Treatment - Surgery

2

Description

In intervention group; after incision of CBD and extraction of stones and intraoperative colangiography; CBD will be closed primarily without T-tube insertion by interrupted absorbable sutures.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Sina Hospital

Full name of responsible person

Abdolhamid Chavoshi khamneh, MD

Street address

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Deputy Dean of Research, Tabriz University of Medical Sciences

Full name of responsible person

Ali Meshkini, MD

Street address

Tariz-Gogasht Ave.

City

Tariz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Deputy Dean of Research, Tabriz University of Medical Sciences

Proportion provided by this source

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

2

Sponsor

Name of organization / entity

Abdolhamid Chavoshi Khamneh, MD

Full name of responsible person

Abdolhamid Chavoshi Khamneh, MD

Street address

Golgasht Ave.

City

Tabriz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Abdolhamid Chavoshi Khamneh, MD

Proportion provided by this source

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

Abdolhamid Chavoshi Khamneh, MD

Position

Resident of General Surgery

Other areas of specialty/work

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Tariz University of Medical Sciences

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Position

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