

# 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

chavoshiab@tbzmed.ac.ir

##### 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 cholangiography

### 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**

Tabriz

#### **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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Abdolhamid Chavoshi Khamneh, MD

**Position**

Resident of General Surgery

**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*