

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 Jun 2026

### Effect of N-Acetyl Cysteine on liver and kidney function tests after surgical bypass in obstructive jaundice patients

#### Protocol summary

##### Summary

The aim of this study is to investigate the effect of N-Acetyl cysteine infusion on improvement of liver and kidney function tests after bypass surgery in patients with obstructive jaundice. 30 patients referred with a diagnosis of obstructive jaundice to Imam Reza hospital, Tabriz, Iran, from March 2106 until the end of september 2016 who need a Bypass surgery (including all cases of cholecystojejunostomy, choledochodeudenostomy or choledochojejunostomy) are recruited for this study and randomly assigned into two groups. For the study group, besides the standard supporting treatments, immediately after the surgery N-acetylcysteine infusion will be started by a dose of 200mg/kg for the first 8 hours and then infusion of a dose of 100 mg/kg will be continued for the next 16 hours. The same order will be repeated in the second 24 hours. Primary outcome measures are serum bilirubin (direct, indirect and total), liver enzymes (ALT, AST), alkaline phosphatase, Gamma glutamyl transferase, creatinine during hospitalization on days 1, 3, 5, 7, 14, 21 and 30 after the surgery and secondary outcomes will be death, need for inotropes, need for dialysis, need for mechanical ventilation, pneumonia, liver encephalopathy and need for liver transplantation.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016041016473N7**  
Registration date: **2016-05-07, 1395/02/18**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2016-05-07, 1395/02/18

#### 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

2016-03-20, 1395/01/01

#### Expected recruitment end date

2016-09-20, 1395/06/30

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Effect of N-Acetyl Cysteine on liver and kidney function tests after surgical bypass in obstructive jaundice patients

#### Public title

Effect of N-Acetyl Cysteine on liver and kidney function tests after surgical bypass in obstructive jaundice patients

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

Inclusion criteria: Age above 18 years and below 75; unable to treat with ERCP or radiologic intervention;

common bile diameter over 10 mm; no indication for resection of obstructive jaundice (choledochal cyst or Whipple procedure); bilirubin level over 5 mg/dl  
Exclusion criteria: possibility of surgical resection (Whipple procedure or bile duct tumor resection); any contraindication for acetylcysteine injection (e.g. asthma, bronchospasm, angioedema or known hypersensitivity); liver cirrhosis or need for liver transplant according to clinical or surgical findings for any reason; known renal failure or heart failure; need for mechanical ventilation before surgery, septic shock resistant to inotrope (Systolic blood pressure less than 90) before surgery; preoperative biliary drainage by ERCP or radiologic intervention; liver enzymes (ALT, AST) greater than 10 times the normal; acute viral hepatitis or any history of drug toxicity; known liver disease such as autoimmune hepatitis; hemolysis cases

**Age**

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

**Gender**

Both

**Phase**

2-3

**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, Tabriz, Iran

**City**

Tabriz

**Postal code****Approval date**

2016-02-01, 1394/11/12

**Ethics committee reference number**

tbzmed.rec.1394.1125

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

Obstruction of bile duct

**ICD-10 code**

K83.1

**ICD-10 code description**

Obstruction of bile duct

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

Aspartate aminotransferase

**Timepoint**

Preoperative and postoperative days 1, 3, 5, 7, 10, 14, and 30

**Method of measurement**

Measurement of serum level

**2****Description**

Alanine aminotransferase

**Timepoint**

Preoperative and postoperative days 1, 3, 5, 7, 10, 14, and 30

**Method of measurement**

Measurement of serum level

**3****Description**

Alkaline phosphatase

**Timepoint**

Preoperative and postoperative days 1 3 .5 .7 .10 .14

**Method of measurement**

Measurement of serum level

**4****Description**

Bilirubin

**Timepoint**

Preoperative and postoperative days 1, 3, 5, 7, 10, 14, and 30

**Method of measurement**

Measurement of serum level

**5****Description**

INR

**Timepoint**

Preoperative and postoperative days 1, 3, 5, 7, 10, 14, and 30

**Method of measurement**

Blood test

## 6

### **Description**

Gamma glutamyl transferase

### **Timepoint**

Preoperative and postoperative days 1 3 5 .7 .10 .14

### **Method of measurement**

Measurement of serum level

## 7

### **Description**

Blood urea nitrogen

### **Timepoint**

Preoperative and postoperative days 1, 3, 5, 7, 10, 14, and 30

### **Method of measurement**

Measurement of serum level

## 8

### **Description**

Creatinine

### **Timepoint**

Preoperative and postoperative days 1 3 5 .7 .10 .14

### **Method of measurement**

Measurement of serum level

## **Secondary outcomes**

## 1

### **Description**

Mortality

### **Timepoint**

Up to 30 days after surgery.

### **Method of measurement**

From clinical records and postdischarge follow up

## 2

### **Description**

Need for dialysis

### **Timepoint**

After the operation time up to 30 days after surgery.

### **Method of measurement**

By clinical records and postdischarge followup

## 3

### **Description**

Need for mechanical ventilation

### **Timepoint**

up to 30 days after surgery.

### **Method of measurement**

By clinical records and postdischarge followup

## 4

### **Description**

Pneumonia

### **Timepoint**

After the operation till discharge

## **Method of measurement**

By clinical records

## 5

### **Description**

Need for inotropes

### **Timepoint**

After the operation till discharge

### **Method of measurement**

By clinical records

## 6

### **Description**

Need for liver transplantation

### **Timepoint**

After the operation till discharge or death

### **Method of measurement**

By clinical records

## 7

### **Description**

Hepatic encephalopathy

### **Timepoint**

After the operation till discharge or death

### **Method of measurement**

By clinical records

## **Intervention groups**

## 1

### **Description**

Intervention Group: N-acetylcysteine infusion for the first 48 hours plus standard treatment (hydration plus antibiotics after the surgery)

### **Category**

Treatment - Drugs

## 2

### **Description**

Control Group: Standard treatment only (hydration plus antibiotics after the surgery)

### **Category**

Treatment - Drugs

## **Recruitment centers**

## 1

### **Recruitment center**

#### **Name of recruitment center**

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 Science

**Full name of responsible person**

Dr 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 Science

**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**

Dr Farzad Kakaei

**Position**

Visceral Transplant Surgeon, Associate Professor

**Other areas of specialty/work**

**Street address**

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**Web page address**

## Person responsible for scientific inquiries

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## Person responsible for updating data

### Contact

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### Other areas of specialty/work

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### City

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### Postal code

### Phone

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### Fax

### Email

fkakaei@tbzmed.ac.ir

### 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*