Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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 sameorder 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 treta 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
Imam Reza Hospital, Golgasht Street
City
Tabriz
Postal code
Phone
+98 41 3334 1317
Fax
Email
fkakaei@tbzmed.ac.ir
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tabriz University Of Medical Sciences
Full name of responsible person
Farzad Kakaei
Position
Visceral Transplant Surgeon, Associate professor
Other areas of specialty/work
Street address
Surgery group, Imam Reza hospital, Golgasht Street
City
Tabriz
Postal code
5166614695
Phone
+98 41 3334 1317
Fax
Email
fkakaei@tbzmed.ac.ir
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Tabriz University of Medical Science
Full name of responsible person
Dr Farzad Kakaei
Position
Visceral Transplant Surgeon/Associate professor
Other areas of specialty/work
Street address
Imam Reza hospital, Golgasht Street
City
Tabriz
Postal code
Phone
+98 41 3334 1317
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