

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

22 Jun 2026

### The comparison of effect of Mannitol infusion and N Acetyl Cysteine on liver function in patients undergoing partial hepatectomy

#### Protocol summary

2018-05-15, 1397/02/25

#### Study aim

The comparison of effect of Mannitol infusion and N Acetyl Cysteine on liver function in patients undergoing partial hepatectomy

#### Design

The trial is functional, randomised two arm parallel groups, double blinded post op care and outcome assessment.

#### Settings and conduct

The trial has been done in Golestan Hospital, Ahvaz University of Medical Science. The surgeon, the patient and the assessor were kept blind of the used medication. The randomization method of using medicine was done alternatively, starting with Mannitol infusion for first patient and went on.

#### Participants/Inclusion and exclusion criteria

ASA class 1 & ASA class 2, Age between 16 to 60, No mortal disease, CHILD-POUGH Score 1

#### Intervention groups

Two different groups of patients with 6 participants suffering from liver disease who have been candidate for partial hepatectomy surgery, were chosen randomly and a specific medication was used for each group.

#### Main outcome variables

Liver enzymes; coagulation profile; acid base profile

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180221038809N1**

Registration date: **2018-05-15, 1397/02/25**

Registration timing: **retrospective**

Last update: **2018-05-15, 1397/02/25**

Update count: **0**

##### Registration date

#### Registrant information

##### Name

Masuomeh Alizadeh

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 74 3232 4568

##### Email address

alizadeh.ma@ajums.ac.ir

#### Recruitment status

##### Recruitment complete

#### Funding source

#### Expected recruitment start date

2018-03-11, 1396/12/20

#### Expected recruitment end date

2018-05-10, 1397/02/20

#### Actual recruitment start date

2018-03-16, 1396/12/25

#### Actual recruitment end date

2018-05-15, 1397/02/25

#### Trial completion date

empty

#### Scientific title

The comparison of effect of Mannitol infusion and N Acetyl Cysteine on liver function in patients undergoing partial hepatectomy

#### Public title

The effect of N\_Acetyl cysteine on hepatectomy outcome

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

age ASA class1 & ASA class 2 No mortal clinical illness

##### Exclusion criteria:

ASA class 3 & ASA class 4 Sever coagulopathy ESRD  
Cirrhosis

### Age

From **15 years** old to **60 years** old

### Gender

Both

### Phase

2

### Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

### Sample size

Target sample size: **12**

Actual sample size reached: **12**

### Randomization (investigator's opinion)

Not randomized

### Randomization description

### Blinding (investigator's opinion)

Single blinded

### Blinding description

Healthcare provider and investigator are the same person. Outcome assessor is blind.

### Placebo

Not used

### Assignment

Parallel

### Other design features

No special feature

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Ahvaz University of Medical Sciences

##### Street address

No.16, Shaghayegh Building., Esfahan Ave., Esfand Square., Golestan., Ahvaz., Khozestan

##### City

Ahvaz

##### Province

Khouzestan

##### Postal code

75817\_83338

##### Approval date

2018-01-27, 1396/11/07

##### Ethics committee reference number

IR.AJUMS.REC.1396.922

## Health conditions studied

### 1

#### Description of health condition studied

Hepatic mass; Hepatic trauma; Partial hepatectomy

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

Liver enzymes; Coagulation profile; Acid-Base profile

#### Timepoint

Lab data during operation, 6,12,24 hrs and 3 days after surgery

#### Method of measurement

IU/L for liver enzymes, (Mg/dl for PT, PTT, INR), PH For asidosis

## Secondary outcomes

### 1

#### Description

Bun and Cr was checked.

#### Timepoint

Bun & Cr data were checked 6, 12 and 24 hrs after surgery

#### Method of measurement

Blood sampling

## Intervention groups

### 1

#### Description

N acetyl cystein is an amino acid with a sulfur base and thiol. Drug is in form of 2gr/ ml vials and was injected by dose of 100mg/kg before hepatic artery clamping intraoperatively to group 1 pateints.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Ahvaz University of Medical Science, Golestan Hospital

##### Full name of responsible person

Masoomeh Alizadeh

##### Street address

No. 16, Shaghayegh Building., Esfahan Ave., Esfand Square., Golestan., Ahvaz., Khozestan

##### City

Ahvaz

##### Province

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##### Postal code

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**Phone**

+98 74 3232 4568

**Email**

dr.alizadeh.92@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Mohammad Badavi

**Street address**

Mr Mohammad Badavi office., Commite of research.,  
University of Medicine., Jundishapoor University of  
Medical Science., Farvardin bolvard., Golestan.,  
Ahvaz., Khozestan

**City**

Ahvaz

**Province**

Khouzestan

**Postal code**

61357\_15794

**Email**

badavim@yahoo.com

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Ahvaz University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

Public

**Domestic or foreign origin**

Domestic

**Category of foreign source of funding**

*empty*

**Country of origin**

**Type of organization providing the funding**

Academic

## Person responsible for general inquiries

#### Contact

**Name of organization / entity**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Masoomah Alizadeh

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Medical Education

**Street address**

No.16, Shaghayegh building., Esfahan Ave.,

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## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**

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**Position**

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**Full name of responsible person**

Masoomah Alizadeh

**Position**

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**Latest degree**

Medical doctor

**Other areas of specialty/work**

Anesthesiology

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**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available