

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

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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.,
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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

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Person responsible for scientific inquiries

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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