# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

01 Jul 2026

## Comparison of N-acetyl cysteine vs saline on liver function on general anesthesia with isoflurane in Arak Vali-e-Asr hospital

## Protocol summary


**Summary**

Purpose: the purpose of this study is evaluation of N-acetyl cysteine on liver function on general anesthesia with isoflurane. Plan: randomized, double-blind, controlled trial study.Trial phase 3. Inclusion criteria: age between 20 to 60 years old; ASA I or II; Elective surgery took 1-3 hours(except surgery on the liver and biliary tract). Exclusion: Underlying cardiovascular, pulmonary , renal , hepatic , endocrine diseases; Taking warfarin , aspirin , NSAIDS, vitamins, corticosteroids, Immuno-Suppressive Drug or any medications interfere with liver function;History of drug abuse , alcohol , cigarettes.Target sample size: 68.Interventions:first group will receive 150 mg/kg N-acetyl cysteine in 250 ml normal saline and second group will receive 250 ml normal saline and use isoflurane for maintenance of anesthesia in both group.Data collector will not inform the patient information and patient groups will not inform about their position in the group. Primary outcome:AST,ALT,LDH level in 1 and 24 h after surgery.


## General information

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT2014091919199N2**
Registration date: **2015-04-12, 1394/01/23**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

**Registration date**

2015-04-12, 1394/01/23

**Registrant information**

**Name**

Saber Akhtaran

**Name of organization / entity**

Arak University of Medical Sciences

**Country**

Iran (Islamic Republic of)

**Phone**

+98 86 3313 6055

**Email address**

dr.akhtaran@arakmu.ac.ir

**Recruitment status**

**Recruitment complete**

**Funding source**

Arak University of Medical Sciences

**Expected recruitment start date**

2014-04-15, 1393/01/26

**Expected recruitment end date**

2015-04-15, 1394/01/26

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Comparison of N-acetyl cysteine vs saline on liver function on general anesthesia with isoflurane in Arak Vali-e-Asr hospital

**Public title**

Effect of N-acetyl cysteine on hepatitis risk reduction after anesthesia

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

Inclusion criteria: age between 20 and 60 years old; ASA I or II; Elective surgery took 1-3 hours(except surgery on the liver and biliary tract). Exclusion: Underlying cardiovascular, pulmonary , renal , hepatic , endocrine diseases; Taking warfarin , aspirin , NSAIDS, vitamins, corticosteroids, Immuno-Suppressive Drug or any medications interfere with liver function;History of drug

abuse, alcohol, cigarettes; History of hepatitis C, B; History of IBD, malabsorption; history of abdominal surgery 5 years ago.

**Age**
From **20 years** old to **60 years** old

**Gender**
Both

**Phase**
3

**Groups that have been masked**
*No information*

**Sample size**
Target sample size: **68**

**Randomization (investigator's opinion)**
Randomized

**Randomization description**

**Blinding (investigator's opinion)**
Double blinded

**Blinding description**

**Placebo**
Used

**Assignment**
Parallel

**Other design features**
In a double-blind clinical trial ,patients were randomly divided in two groups,According to medical ethics will obtain consent to enter the study of patients.Data collector will not inform the patient information and patient groups will not inform about their position in the group.

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**
Ethics committee of Arak University of medical sciences

**Street address**
Arak University Of Medical Science, Basij Sq.

**City**
Arak

**Postal code**

**Approval date**
2014-01-29, 1392/11/09

**Ethics committee reference number**
92-158-6

## Health conditions studied

### 1

**Description of health condition studied**
liver toxicity

**ICD-10 code**
K71

**ICD-10 code description**
Toxic liver disease

## Primary outcomes

### 1

**Description**
AST

**Timepoint**
Before surgery, 1 and 24 h after it

**Method of measurement**
With MAK055 Sigma laboratory kit

### 2

**Description**
ALT

**Timepoint**
Before surgery, 1 and 24 h after it

**Method of measurement**
With MAK052 Sigma laboratory kit

### 3

**Description**
LDH

**Timepoint**
Before surgery, 1 and 24 h after it

**Method of measurement**
With MAK066 Sigma laboratory kit

## Secondary outcomes

### 1

**Description**
PT

**Timepoint**
Before surgery, 1 and 24 h after it

**Method of measurement**
PT kit \ medical diagnosis laboratory

### 2

**Description**
PTT

**Timepoint**
Before surgery, 1 and 24 h after it

**Method of measurement**
Stago PTT laboratory kit

### 3

**Description**
mean arterial pressure

**Timepoint**
before and after induction, after intubation and every 10 minute

**Method of measurement**
sphygmomanometer

**4**

**Description**
heart rate
**Timepoint**
before and after induction, after intubation and every 10 minute
**Method of measurement**
measuring the number of times their heart beats each minute by touching the pulse

**5**

**Description**
o2 saturation
**Timepoint**
before and after induction, after intubation and every 10 minute
**Method of measurement**
measuring of o2 saturation by pulse oximetry

## Intervention groups

**1**

**Description**
In intervention group patients will receive 150 mg/kg N-Acetyl cysteine with 250 ml normal saline in single IV dose and isoflurane will be used for maintenance anesthesia. We injected above mentioned solution before induction.All patients will pre-oxygenated with 100% oxygen.Patients will take Fentanyl 2mc/kg, 3-6 mg/kg sodium thiopental ( logi Chem UK)and 0/5 mg/kg Atracurium(Alborz darou).All patients will take 1 mg/kg fentanyl and 0/2 mg/kg atracurium during anesthesia every 40 minutes.Trial group will receive 12/5 mg/kg N-acetyl cysteine during surgery.
**Category**
Treatment - Drugs

**2**

**Description**
In control group patients will receive only 250 ml normal salinein single IV dose and isoflurane will used for maintenance anesthesia.we injected above solution before induction.All patients will pre-oxygenated with 100% oxygen.Patients will take Fentanyl 2mc/kg, 3-6 mg/kg sodium thiopental ( logi Chem UK)and 0/5 mg/kg Atracurium(Alborz darou).All patients every 40 minutes will take 1 mg/kg fentanyl and 0/2 mg/kg atracurium during anesthesia
**Category**
Treatment - Drugs

## Recruitment centers

**1**

**Recruitment center**
**Name of recruitment center**
Vali-e-Asr Hospital
**Full name of responsible person**
Dr. Saber Akhtaran
**Street address**
Vali-e-Asr Hospital, Vali-e-Asr Sq.
**City**
Arak

## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Arak University of Medical Sciences, Vice chancellor for research
**Full name of responsible person**
Dr.Ali Asghar Yaghoobi
**Street address**
Arak University Of Medical Science, Basij Sq.
**City**
Arak
**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Arak University of Medical Sciences, Vice chancellor for research
**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**
Arak University of Medical Sciences
**Full name of responsible person**
Dr.Saber Akhtaran
**Position**
Resident of Anesthesiology and Intensive Care
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## Person responsible for scientific inquiries

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## Person responsible for updating data

**Contact**

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**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*