Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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

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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
Other areas of specialty/work
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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