# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

17 Sep 2026

## Comparison and examination of the effect of vitamin E on the improvement of hepatic indexes in patients with acute hepatitis A

## Protocol summary

**Study aim**

Comparison and examination of the effect of vitamin E on the improvement of hepatic indexes in patients with acute hepatitis A

**Design**

100 patients with hepatitis A attending in Imam Khomeini hospital, Zabol, will be allocated to intervention (vitamin E) and control using random number table. Allocation will be performed as simple random sampling.

**Settings and conduct**

A checklist will be completed for each patient attending in Imam Khomeini clinic in Zabol including demographic, clinical anthropometric and biochemical characteristics. These information will be provided from patients or their parents or their files. Liver enzymes including Aspartate Aminotransferase and Alanine aminotransferase measured in the laboratory of Imam Khomeini hospital, Zabol using autoanalyzer

**Participants/Inclusion and exclusion criteria**

Inclusion criteria:Having Coagulopathy (<PT INR), Encephalopathy,Intolerance po, Anti-HAV positive. Exclusion criteria: HAV positive for up to 6 months, Having a abdominal pain, changing the color of the urine, changing the color of the stool, jaundice. Taking any medication

**Intervention groups**

Patients will be referred to the physician after allocating into control (100 patients) and intervention (100 patients) groups. The intervention group including patients with hepatitis A will receive vitamin E (400 mg single dose per day) after primary examination by the physician. Control group including patients with hepatitis A receiving no drug.

**Main outcome variables**

Measurment of liver enzymes including aspartate aminitransferase and Alanine aminotransferase.

## General information

**Reason for update**

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT20171205037752N1**
Registration date: **2018-02-01, 1396/11/12**
Registration timing: **retrospective**

Last update: **2018-02-01, 1396/11/12**
Update count: **0**

**Registration date**

2018-02-01, 1396/11/12

**Registrant information**

**Name**

Elahe Bahmadisani

**Name of organization / entity**

**Country**

Iran (Islamic Republic of)

**Phone**

+98 54 3223 2183

**Email address**

sanipharmacy@gmail.com

**Recruitment status**

**Recruitment complete**

**Funding source**

**Expected recruitment start date**

2016-10-01, 1395/07/10

**Expected recruitment end date**

2017-10-02, 1396/07/10

**Actual recruitment start date**

2016-10-01, 1395/07/10

**Actual recruitment end date**

2017-08-01, 1396/05/10

**Trial completion date**

empty

**Scientific title**

Comparison and examination of the effect of vitamin E on the improvement of hepatic indexes in patients with acute hepatitis A

**Public title**
Evaluation of the improvement effects of Vitamin E on liver indexs in pationts with acute hepatitis A
**Purpose**
Treatment
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
Having Coagulopathy (<PT INR) Encephalopathy intolerance po Anti HAV positive
**Exclusion criteria:**
HAV positive for up to 6 months Having a abdominal pain Change the color of the urine Change the stool color jaundice Taking any medication
**Age**
No age limit
**Gender**
Both

**Phase**
3
**Groups that have been masked**

- Investigator

**Sample size**
Target sample size: **200**
Actual sample size reached: **155**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
The randomization method is simple randomization. The randomization unit is individual and the randomization tool is random number table.
**Blinding (investigator's opinion)**
Single blinded
**Blinding description**
The medicine is prescribed by the doctor, but this study is being reviewed by another investigator.Therefore, the investigator can not diagnose the patient who received the medication.
**Placebo**
Not used
**Assignment**
Parallel
**Other design features**

## Secondary Ids

empty

## Ethics committees

**1**

**Ethics committee**
**Name of ethics committee**
Ethics Committee Zabol University of Medical Sciences
**Street address**
Shahid Rajaee St., Educational Complex of Zabol University of Medical Sciences
**City**
Zabol
**Province**
Sistan-va-Balouchestan
**Postal code**
9861663335
**Approval date**
2017-05-22, 1396/03/01
**Ethics committee reference number**
Zbmu.1.REC.1396.63

## Health conditions studied

**1**

**Description of health condition studied**
Hepatitis A acute
**ICD-10 code**
B15
**ICD-10 code description**
Acute hepatitis A

## Primary outcomes

**1**

**Description**
Measurement of liver enzyme alanine aminotransferase
**Timepoint**
Measuring liver enzyme including Alanine aminotransferase before the intervention and two weeks, one, two, three, four and six months after prescribing vitamin E.
**Method of measurement**
In the laboratory by an auto-analyzer

**2**

**Description**
Measuring the aspartate aminotransferase Liver Enzyme
**Timepoint**
Measuring liver enzyme including aspartate aminitransferase before the intervention and two weeks, one, two, three, four and six months after prescribing vitamin E.
**Method of measurement**
In the laboratory by an auto-analyzer

## Secondary outcomes

empty

## Intervention groups

**1**

**Description**
Intervention group: Vitamin E pearls (Alpha-Tocopherol) with chemical formula as of C29H50O2 , 400 mg per day for six months.
**Category**

Treatment - Drugs

**2**

**Description**
Control group: Not receiving any treatment.
**Category**
N/A

## Recruitment centers

**1**

**Recruitment center**
**Name of recruitment center**
Clinic of Imam Khomeini Hospital in Zabol
**Full name of responsible person**
Elahe Bahmadisani
**Street address**
Imam Khomeini Specialized Clinic, In front of the Central Building of Zabol University of Medical Sciences, Jahad Square, Zabol, Iran.
**City**
Zabol
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Sistan-va-Balouchestan
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9861673137
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sanipharmacy91@gmail.com
**Web page address**
http://www.zbmu.ac.ir

## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Zabol University of Medical Sciences
**Full name of responsible person**
Kaveh Tabrizian
**Street address**
Shahid Rajaee St., Educational Complex of Zabol University of Medical Sciences
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K-Tabrizian2005@yahoo.com
**Web page address**
http://www.zbmu.ac.ir
**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Zabol 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**
Zabol University of Medical Sciences
**Full name of responsible person**
Elahe Bahmadisani
**Position**
Student
**Latest degree**
A Level or less
**Other areas of specialty/work**
Medical Pharmacy
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## Person responsible for scientific inquiries

**Contact**
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Iraj Shahramian
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## Person responsible for updating data

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student
**Latest degree**
A Level or less
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sanipharmacy@gmail.com

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**
No - There is not a plan to make this available
**Justification/reason for indecision/not sharing IPD**
Because of ethical issues and the confidentiality of information
**Study Protocol**
No - There is not a plan to make this available
**Statistical Analysis Plan**
No - There is not a plan to make this available
**Informed Consent Form**
No - There is not a plan to make this available
**Clinical Study Report**
No - There is not a plan to make this available
**Analytic Code**
No - There is not a plan to make this available
**Data Dictionary**
No - There is not a plan to make this available