

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jul 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

Measurement of liver enzymes including aspartate aminotransferase 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 indexes in patients 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 Rajaei 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 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

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.

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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

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Shahid Rajaei St., Educational Complex of Zabol University of Medical Sciences

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<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

Name of organization / entity

Zabol University of Medical Sciences

Full name of responsible person

Iraj Shahramian

Position

Associate Professor

Latest degree

Subspecialist

Other areas of specialty/work

Pediatrics

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Person responsible for updating data**Contact****Name of organization / entity**

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Full name of responsible person

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Position

student

Latest degree

A Level or less

Other areas of specialty/work

Medical Pharmacy

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University of Medical Sciences**City**

Zabol

Province**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