

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 2026

Comparison between efficacy and adverse effects of Ursodeoxy cholic acid, silymarin and vitamin E and placebo (Folic acid) in Anticonvulsive drugs induced hypertransaminasemia in 4 months to 13 years old patients

Protocol summary

Summary

This study is a residency thesis and a randomized placebo-controlled trial. The aim of it is evaluation of efficacy of hepatoprotective drugs including Ursodeoxy cholic acid, Silymarin and Vitamin E in drug induced hepatitis and comparison of them and with placebo. Every patient with significant hypertransaminasemia (rise of transaminases behind the twice of upper normal limits) after rule out of common and important causes of hepatitis such as viral, autoimmune and metabolic diseases and after rule out of anatomic abnormalities was recruited in study. Any patient with other possible causes of hypertransaminasemia and without parents consent or with transient course (less than 2 months hypertransaminasemia) was excluded. 100 patients aged 4mo-13yr with persistent hypertransaminasemia from pediatric neurology clinic of Valiasr Hospital after rule out of other etiologies were randomized based on block randomization method to 4 parallel groups and allocated to receive Ursodeoxy cholic acid in dose of 10mg/kg/day or Silymarin in dose of 5mg/kg/day or Vitamin E in dose of 1mg(IU)/kg/day up to 50 mg or Folic acid 1mg/day as placebo for one month. All parents gave consent. Transaminases were checked before and one month after intervention and one month after cessation of it and their levels were compared between groups and in each group as before and after variables. None of our patients showed hepatic functional defects.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015010711392N2**

Registration date: **2015-02-02, 1393/11/13**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-02-02, 1393/11/13

Registrant information

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Masoumeh Asgarshirazi

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Research deputy of Tehran University of Medical Sciences

Expected recruitment start date

2012-06-21, 1391/04/01

Expected recruitment end date

2013-06-22, 1392/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison between efficacy and adverse effects of

Ursodeoxy cholic acid, silymarin and vitamin E and placebo (Folic acid) in Anticonvulsive drugs induced hypertransaminasemia in 4 months to 13 years old patients

Public title

Comparison between Ursodeoxy cholic acid, silymarin and vitamin E in Anticonvulsive drugs induced hypertransaminasemia

Purpose

Treatment

Inclusion/Exclusion criteria

Patients with age between 4 months to 13 years in pediatric neurology ward and clinic of Valiasr hospital with anticonvulsive induced hypertransaminasemia after rule out of common causes of hepatitis such as viral, autoimmune, metabolic and after rule out of anatomical defects have been included. Any patient without parents consent was excluded and any patient with spontaneous decline in transaminases were excluded too.

Age

From **4 months** old to **13 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Deputy of Tehran University of Medical Sciences

Street address

Poursina street, Keshavarz Blvd., Tehran

City

Tehran

Postal code

141761351

Approval date

2012-06-20, 1391/03/31

Ethics committee reference number

1391-1075

Health conditions studied

1

Description of health condition studied

drug induced hypertransaminasemia

ICD-10 code

R74.0

ICD-10 code description

abnormal serum enzyme levels

Primary outcomes

1

Description

Transaminases levels

Timepoint

one month after intervention and one month after cessation of it

Method of measurement

serum transaminases with one standard kit and in International Unite per litre

Secondary outcomes

1

Description

No rebound elevation of serum transaminases after cessation of intervention

Timepoint

one month after intervention cessation

Method of measurement

with standard lab kit and in International Unite per litre

Intervention groups

1

Description

prescription of Folic acid as placebo in dose of 1mg/day in drug-induced hypertransaminasemia

Category

Treatment - Drugs

2

Description

prescription of Ursodeoxy cholic acid in dose of 10mg/kg/day in drug induced hypertransaminasemia

Category

Treatment - Drugs

3

Description

prescription of Silymarin in dose of 5mg/kg/day for

anticonvulsive induced hypertransaminasemia

Category

Treatment - Drugs

4

Description

prescription of Vitamin E in dose of 1mg or IU/kg/day up to 50mg/day for drug induced hypertransaminasemia

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Pediatric neurology ward and clinic of Valiasr Hospital, Imam Khomeini Hospital complex

Full name of responsible person

Masoumeh Asgarshirazi

Street address

Pediatrics ward, Valiasr Hospital, Imam Khomeini Hospital complex-Keshavarz Blvd- Tehran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-chancellor for research-Medical school of Tehran University of Medical Sciences

Full name of responsible person

Dr.Shahin Akhondzade

Street address

Poursina street, Keshavarz Blvd.,Tehran

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Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice-chancellor for research-Medical school of Tehran University of Medical Sciences

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

School of Medicine,Tehran University of Medical Sciences

Full name of responsible person

Masoumeh Asgarshirazi

Position

Pediatric Gastroenterologist,Assistant professor

Other areas of specialty/work

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Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

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Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty