

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation the protective effect of Ursodeoxycholic Acid on hepatic damage in patients with neurological diseases treated with Sodium Valporat

Protocol summary

Study aim

Evaluation the protective effect of Ursodeoxycholic Acid on hepatic damage

Design

A double-blind, randomized clinical trial, with parallel groups Patients are randomly assigned to two groups of intervention and control (each group of 120 patients). The control group receive placebo + valproate sodium (15 mg/ kg/day). The intervention group receive sodium valproate + Ursodeoxycholic Acid (each with a dose of 15 mg/kg/day). The outcome is alternation in liver enzymes measured at the beginning and end of the study.

Settings and conduct

The study is conducted in Amir-Al-Momenin Hospital in Zabol. Patients are randomly assigned to control and intervention groups. Researcher and patients are blinded to the intervention in each group by using placebo.

Participants/Inclusion and exclusion criteria

The study population includes patients with neurological disorders treated sodium valproate referred to Amir-Al-Momenin Hospital of Zabol city. Inclusion criteria: willingness to participate, lack of alcohol intake, systemic diseases, chronic and acute liver disorders (hepatitis B, C, etc.), cirrhosis, celiac disease, diabetes, high blood pressure, cardiovascular disease, lung disease, kidney disease, not being pregnancy or in lactation, not taking metformin and hepatotoxic drugs, no antibiotic use during one week before entering into the study, no history of surgery in the recent year, Lack of weight loss in the last 3 months. Exclusion criteria: Taking antibiotics more than one week during the study period, willingness to withdraw from the study, not taking more than 10% of the prescribed capsules in each follow up.

Intervention groups

Control group: placebo + sodium valproate (15 mg / kg / day) Intervention group: Sodium valproate (15 mg / kg /

day) + Ursodeoxycholic Acid (15 mg / kg / day)

Main outcome variables

Liver functional tests

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181228042156N1**

Registration date: **2019-05-06, 1398/02/16**

Registration timing: **registered_while_recruiting**

Last update: **2019-05-06, 1398/02/16**

Update count: **0**

Registration date

2019-05-06, 1398/02/16

Registrant information

Name

Rosa Mostafaiy

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 54 3229 5147

Email address

m.baziali@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-01-21, 1397/11/01

Expected recruitment end date

2020-02-20, 1398/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation the protective effect of Ursodeoxycholic Acid on hepatic damage in patients with neurological diseases treated with Sodium Valporat

Public title

The protective effect of Ursodeoxycholic Acid in prevention of hepatic damage in neurological patients treated with Sodium Valporat

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Willing to participate in the study Definite diagnosis of migraine, bipolar disorder, or epilepsy Age of <18 years Not being pregnant or lactating

Exclusion criteria:

Not willing to participate in the study Systemic diseases, acute or chronic hepatic diseases (hepatitis B, C, cirrhosis), diabetes, celiac, hypertension, cardiovascular diseases, pulmonary diseases, renal diseases Age > 18 years old Using hepatotoxic drugs and antibiotics Not taking more than 10% of the administrated Ursodeoxycholic Acid

Age

To 18 years old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: 240

Randomization (investigator's opinion)

Randomized

Randomization description

The patients were randomized based on a random sequence of numbers (using <https://www.randomizer.org> online tool).

Blinding (investigator's opinion)

Double blinded

Blinding description

This study was double-blinded in which the researcher and patients who received the drug, as well as the researcher evaluating the outcome were unaware of the type of administrated therapy.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Zabol University of Medical Sciences

Street address

Kilometer 5 of Zabol-Zahedan highway, Amir-Al-Momenin Hospital, Zabol, Iran

City

Zabol

Province

Sistan-va-Balouchestan

Postal code

9861979917

Approval date

2018-12-24, 1397/10/03

Ethics committee reference number

IR.ZBMU.REC.1397.116

Health conditions studied**1****Description of health condition studied**

Migraine

ICD-10 code

G43

ICD-10 code description

Migraine

2**Description of health condition studied**

Epilepsy

ICD-10 code

G40

ICD-10 code description

Epilepsy and recurrent seizures

3**Description of health condition studied**

Bipolar disorder

ICD-10 code

F31

ICD-10 code description

Bipolar disorder

Primary outcomes**1****Description**

Abnormal liver functional tests

Timepoint

The outcomes are measured 3, 6, and 9 months after the initiation of the intervention.

Method of measurement

Using serum separated from venous blood and ELISA method

Secondary outcomes

empty

Intervention groups

1

Description

Control group: In this group, patients under Sodium Valproate treatment (15 mg/kg daily) receive placebo. Liver functional tests in this group are measured at the beginning of the study, and after 3, 6 and 9 weeks from the beginning of the intervention.

Category

Placebo

2

Description

Intervention group: In this group, patients treated with Sodium Valproate (15 mg/kg daily) are concomitantly treated with Ursodeoxycholic Acid (15 mg/kg daily) acid. Liver functional tests in this group are measured at the beginning of the study, and after 3, 6 and 9 weeks from the beginning of the intervention.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Amir-Al-Momenin hospital of Zabol

Full name of responsible person

Roza Mostafaei

Street address

Amir-Al-Momenin hospital, Kilometer 5 of Zabol-Zahedan highway, Zabol, Iran

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Email

mostafaiy.rosa@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zabol University of Medical Sciences

Full name of responsible person

Khadijeh Rezaee Keikhaei

Street address

Amir-Al-Momenin hospital, Kilometer 5 of Zabol-Zahedan highway, Zabol, Iran

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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

Roza Mostafaei

Position

Pediatric resident

Latest degree

Medical doctor

Other areas of specialty/work

Pediatrics

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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
Zabol University of Medical Sciences

Full name of responsible person
Ali Bazi

Position
Consultant

Latest degree
Master

Other areas of specialty/work
Hematology

Street address
Faculty of Allied Medical Sciences, Zabol University of Medical Sciences, Rajaei Martyr St., Zabol, Iran

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

Data from the patients is collected in forms designed by the researcher and at the end of the study, these forms can be made available to relevant individuals and institutions. The results of the study will also be published as a paper and will be publicly available.

When the data will become available and for how long

2018

To whom data/document is available

Physicians

Under which criteria data/document could be used

For use by doctors and researchers

From where data/document is obtainable

Dr. Iraj Sharamian Email: lr_buper@yahoo.com Phone: +989151917652 Dr. Roza Mostafaei Email: mostafaiy.rosa@gmail.com Phone: +989134408810

What processes are involved for a request to access data/document

By submitting a request via email

Comments