Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Jul 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 Hosptial 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

City

Zabol

Province

Sistan-va-Balouchestan

Postal code

9861979917

Phone

+98 54 3229 5147

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

City

Zabol

Province

Sistan-va-Balouchestan

Postal code

9861979917

Phone

+98 54 3229 5147

Email

mostafaiy.rosa@gmail.com

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

Street address

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

City

Zabol

Province

Sistan-va-Balouchestan

Postal code

9861979917

Phone

+98 54 3229 5147

Email
mostafaiy.rosa@gmail.com

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
Street address
Amir-Al-Momenin hospital, Kilometer 5 of Zabol-Zahedan highway, Zabol, Iran
City
Zabol
Province
Sistan-va-Balouchestan
Postal code
9861979917
Phone
+98 54 3229 5147
Email
Ir_buper@yahoo.com

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, Rajaee Martyr St., Zabol, Iran
City
Zabol
Province
Sistan-va-Balouchestan
Postal code
9861979917
Phone
+98 911 701 5054
Email
m.baziali@gmail.com

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: Ir_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