Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of wheat germ oil on vitamin D levels and changes in liver enzymes in children 2 to 12 years old treated with phenobarbital and sodium valproate referred to Imam Ali Clinic in Shahrekord

Protocol summary

Study aim

Determining the effect of wheat germ oil on vitamin D levels and changes in liver enzymes in children 2 to 12 years old treated with phenobarbital and sodium valproate referred to Imam Ali Clinic in Shahrekord

Design

A total of 120 outpatients referred to a neurology clinic who have been diagnosed with epilepsy and meet the inclusion criteria are included in the study by simple random sampling and include two groups of 60 people consuming sodium valproate and phenobarbital. Each group is divided into two groups of 30 consumers and non-consumers of wheat germ oil. Thus, the four groups are studied as follows: Group 1: Phenobarbital + Vitamin D + Wheat germ oil Group 2: Phenobarbital + Vitamin D + Placebo Group 3: Sodium valproate + Vitamin D + Wheat germ oil Group 4: Sodium valproate + vitamin D + placebo

Settings and conduct

Single blind clinical trial. Vitamin D and liver enzymes of patients will be performed twice and with an interval of 3 months from the start of drug use and Also, children will receive the required daily prophylaxis amount of 400 units of vitamin D at the beginning of treatment, and each group consuming sodium valproate and phenobarbital is divided into two groups. One group treated with a soft capsule of one gram of wheat germ (three daily) In addition to vitamin D will be prophylaxis, and the other group in addition to vitamin D prophylaxis will be placebo completely similar to the soft capsule of wheat germ oil.

Participants/Inclusion and exclusion criteria

Children 2 to 12 years old treated with phenobarbital and sodium valproate

Intervention groups

Four groups are studied as follows: Group 1: Phenobarbital + Vitamin D + Wheat germ oil Group 2: Phenobarbital + Vitamin D + Placebo Group 3: Sodium valproate + Vitamin D + Wheat germ oil Group 4: Sodium valproate + vitamin D + placebo

Main outcome variables

Vitamin D levels Liver enzyme levels

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210319050742N1**
Registration date: **2021-06-04, 1400/03/14**
Registration timing: **prospective**

Last update: **2021-06-04, 1400/03/14**
Update count: **0**

Registration date

2021-06-04, 1400/03/14

Registrant information

Name

Samane Safari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 38 3224 3716

Email address

st-safari.s@skums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-06-22, 1400/04/01

Expected recruitment end date

2021-08-23, 1400/06/01

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of wheat germ oil on vitamin D levels and changes in liver enzymes in children 2 to 12 years old treated with phenobarbital and sodium valproate referred to Imam Ali Clinic in Shahrekord

Public title
The effect of wheat germ oil on vitamin D levels and changes in liver enzymes in children
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Definitive diagnosis of epilepsy Has an age of 2 to 12 years Lack of underlying disease that affects the metabolism of vitamin D and calcium Do not take drugs or drugs that affect the metabolism of calcium and vitamin D. Do not receive oral or injectable vitamin compounds containing vitamin D in the last 3 months. Do not suffer from acute and chronic liver diseases Do not have fatty liver Do not take other drugs that affect the level of liver enzymes
Exclusion criteria:
Change in the definitive diagnosis of epilepsy Existence of underlying diseases that affect the metabolism of vitamin D and calcium Taking medication or drugs that affect calcium and vitamin D metabolism Dissatisfaction of parents Failure to follow instructions and perform tests Changing the treatment protocol Drug allergy Physical disorder that hinders the patient's activity. History of fracture Vitamin D deficiency Low calcium levels Acute and chronic liver diseases Taking other drugs with hepatic metabolism
Age
From **2 years** old to **12 years** old
Gender
Both

Phase
2-3
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **120**
Randomization (investigator's opinion)
Randomized
Randomization description
The randomization method is based on a table of random numbers and blocks of 4 and the study is done in double-blind.
Blinding (investigator's opinion)
Double blinded
Blinding description
Wheat germ oil and placebo have been coded to blind the product. The patient and the researcher are not aware of the type of drug administered.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Shahrekord University of Medical Sciences
Street address
Shahre-Kord University of Medical Sciences, Parastar Ave.
City
Shahrekord
Province
Chahar-Mahal-va-Bakhtiari
Postal code
8816754633
Approval date
2021-04-20, 1400/01/31
Ethics committee reference number
IR.SKUMS.REC.1400.040

Health conditions studied

1

Description of health condition studied
Children treated with phenobarbital and sodium valproate
ICD-10 code
G40
ICD-10 code description
Epilepsy and recurrent seizures

Primary outcomes

1

Description
Liver enzyme levels and vitamin D levels
Timepoint
In two rounds and with an interval of 3 months from the start of taking the drug
Method of measurement
Blood test

Secondary outcomes

empty

Intervention groups

1

Description
Control group: Group 2: Phenobarbital + Vitamin D + Placebo
Category
Treatment - Drugs

2

Description
Intervention group: Group 1: Phenobarbital + Vitamin D + Wheat germ oil
Category
Treatment - Drugs

3

Description
Control group: Group 4: Sodium valproate + vitamin D + placebo
Category
Treatment - Drugs

4

Description
Intervention group: Group 3: Sodium valproate + Vitamin D + Wheat germ oil
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Hajar Hospital, Shahrekord
Full name of responsible person
Anahita Farahzad
Street address
Parastar Aven
City
Shahrekord
Province
Chahar-Mahal-va-Bakhtiari
Postal code
8816754633
Phone
+98 38 3222 0016
Email
st-safari.s@skums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahre-kord University of Medical Sciences
Full name of responsible person
Mehraban Sadeghy
Street address
Shahre-Kord University of Medical Sciences, Parastar Ave.
City
Shahrekord
Province
Chahar-Mahal-va-Bakhtiari
Postal code
8816754633
Phone
+98 38 3222 0016
Email
st-safari.s@skums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahre-kord 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
Shahre-kord University of Medical Sciences
Full name of responsible person
Samaneh Safari
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Pediatrics
Street address
Shahre-Kord University of Medical Sciences, Parastar Ave.
City
Sahrekord
Province
Chahar-Mahal-va-Bakhtiari
Postal code
8816754633
Phone
+98 38 3222 0016
Email
st-safari.s@skums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shahre-kord University of Medical Sciences

Full name of responsible person
Samaneh Safari

Position
Resident

Latest degree
Medical doctor

Other areas of specialty/work
Pediatrics

Street address
Shahre-Kord University of Medical Sciences, Parastar Ave.

City
Shahrekord

Province
Chahar-Mahal-va-Bakhtiari

Postal code
8816754633

Phone
+98 38 3222 0016

Email
st-safari.s@skums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Shahre-kord University of Medical Sciences

Full name of responsible person
Samaneh Safari

Position
Resident

Latest degree
Medical doctor

Other areas of specialty/work
Pediatrics

Street address
Hajar Hospital, Parastar Ave.

City
Shahrekord

Province
Chahar-Mahal-va-Bakhtiari

Postal code
8816754633

Phone
+98 38 3222 0016

Email
st-safari.s@skums.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be 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

Title and more details about the data/document
Only part of the data such as information about the main outcome or the like can be shared.

When the data will become available and for how long
2021-2022

To whom data/document is available
The data will be available only to researchers working in academic and scientific institutions

Under which criteria data/document could be used
I have not decided yet

From where data/document is obtainable
I have not decided yet

What processes are involved for a request to access data/document
I have not decided yet

Comments