

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

The effect of ketogenic diet on the serum levels of ketone bodies and arachidonic acid and their association with oxidative stress indices in children with drug-resistant epilepsy

Protocol summary

Study aim

The Evaluation and comparison of the serum levels of ketone bodies, arachidonic acid, and oxidative stress factors in children with drug-resistant epilepsy before and after the ketogenic diet.

Design

A before and after clinical trial with an interventional group before and after.

Settings and conduct

The samples will be collected before and after the intervention in a -70°C freezer in Pediatric Health Research Center at Tabriz children Hospital. After the sampling, biochemical factors will be evaluated and compared statistically.

Participants/Inclusion and exclusion criteria

Among children under the age of 18 years with drug-resistant epilepsy referring to the neurology department of Tabriz Pediatric Center, 30 patients were randomly selected after the initial diagnosis and confirmation of the disease, and after obtaining the consent will be included in the study (including criteria). Excluding criteria will include pathological underlying diseases affecting the metabolism of the drug, such as liver impairment, renal failure, blood diseases, and malignancies.

Intervention groups

Patients under the supervision of a physician will undergo a six-month course of ketogenic diet, which includes a ratio of 4 to 1 or 3 to 1 (in children of low age) from fat to carbohydrates plus proteins. Three months after the onset of the diet (second-line blood collection) and after the end of six months (third-order blood sampling), blood sampling will be done from the patients.

Main outcome variables

Serum levels of beta-hydroxybutyrate, arachidonic acid, and oxidative stress indices (MDA and 8-OHdG) will be different before and after the ketogenic diet.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20131012014988N4**

Registration date: **2018-05-15, 1397/02/25**

Registration timing: **registered_while_recruiting**

Last update: **2018-05-15, 1397/02/25**

Update count: **0**

Registration date

2018-05-15, 1397/02/25

Registrant information

Name

Mohammad Barzegar

Name of organization / entity

Pediatric Health Research Center, Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 3526 2265

Email address

phrc_mb@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-04-21, 1397/02/01

Expected recruitment end date

2018-10-22, 1397/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of ketogenic diet on the serum levels of ketone bodies and arachidonic acid and their association with oxidative stress indices in children with drug-resistant epilepsy

Public title

The Effect of Ketogenic Diet in the Treatment of Drug-Resistant Epilepsy

Purpose

Basic science

Inclusion/Exclusion criteria**Inclusion criteria:**

Children under the age of 18 with epilepsy Patients referring to the neurology department of Tabriz Children Hospital.

Exclusion criteria:

Having pathological underlying diseases affecting the metabolism of drugs such as liver impairment, renal failure, blood diseases, and malignancies.

Age

To **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

N/A

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Single

Other design features**Secondary Ids**

empty

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

Regional Ethics Committee of Tabriz University of Medical Sciences

Street address

Pediatric Health Research Center, Tabriz Children Hospital, Sheshgelan Street, Tabriz, Iran.

City

Tabriz

Province

East Azarbaijan

Postal code

5136735886

Approval date

2018-02-26, 1396/12/07

Ethics committee reference number

IR.TBZMED.REC.1396.1110

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

Drug-resistant epilepsy

ICD-10 code

G40

ICD-10 code description

Epilepsy and recurrent seizures

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

The serum level of beta-hydroxybutyrate that is the index of the ketone bodies.

Timepoint

At the beginning of the study (before the intervention), three, and six months after the onset of the ketogenic diet.

Method of measurement

Spectrophotometry

2**Description**

Serum level of arachidonic acid that is an unsaturated fatty acid.

Timepoint

At the beginning of the study (before the intervention), three, and six months after the onset of the ketogenic diet.

Method of measurement

Enzyme linked-immunosorbent assay (ELISA)

3**Description**

The serum levels of malondialdehyde (MDA) that is an oxidative stress marker of the lipids.

Timepoint

At the beginning of the study (before the intervention), three, and six months after the onset of the ketogenic diet.

Method of measurement

Spectrophotometry

4**Description**

The serum levels of 8-Hydroxydeoxyguanosine (8-OHdG)

that is an oxidative stress marker of DNA.

Timepoint

At the beginning of the study (before the intervention), three, and six months after the onset of the ketogenic diet.

Method of measurement

Enzyme linked-immunosorbent assay (ELISA)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The patients under the supervision of a physician will undergo a six-month course of ketogenic diet, which includes a ratio of 4 to 1 or 3 to 1 (in children of low age) from fat to carbohydrates plus proteins. That means about 90 percent of the daily calories needed in this diet will come from fat.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Tabriz Children Hospital

Full name of responsible person

Mohammad Barzegar

Street address

Pediatric Health Research Center, Children Hosp.

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phrc_mb@tbzmed.ac.ir

Web page address

<http://childrenhospital.tbzmed.ac.ir/>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Abolghasem Jouyban

Street address

International Relations Office, No 2 Central Building, Tabriz University of Medical Sciences, University Street, Tabriz, Iran

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research-vice@tbzmed.ac.ir

Web page address

<http://researchvice.tbzmed.ac.ir/>

Grant name

Grant code / Reference number

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

No

Title of funding source

Office of the Vice Chancellor for Research of Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Moahhamad Barzegar

Position

Pediatric Neurologist

Latest degree

Subspecialist

Other areas of specialty/work

Neuroscience

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Moahamad Barzegar

Position

Pediatric Neurologist

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Other areas of specialty/work

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Full name of responsible person

Dr. Sina Raeisi

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Biochemistry

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be 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

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

Informed Consent Form

Undecided - It is not yet known if there will be 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

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