

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jul 2026

Efficacy and complication of ketogenic diet and modified therapy in pediatric's refractory epilepsy ketogenic diet on childhood refractory epilepsy

Protocol summary

Study aim

Determine the amount of seizure reduction after the start of the ketogenic diet

Design

In order to determine the sample size, 35 children with refractory epilepsy referring to Neurology Clinic of Tabriz University of Medical Sciences were selected by simple sampling and Access will be selected and will be included in the study.

Settings and conduct

Selected patients are admitted to Tabriz Children's Hospital and begin a ketogenic diet and will be discharged from the hospital after taking the diet and continue the regimen outside the hospital and will be monitored regularly.

Participants/Inclusion and exclusion criteria

inclusion criteria : -age : 2 - 15 years -lack of seizure control using 2 first line anti epileptic drugs -on average 1 attack per month -there is no chronic disease such as liver disease or diabetes -there is no progressive neurologic disorder -parental training -informed consent
exclusion criteria: -liver disease -progressive neurologic disorders - inborn error of metabolism with ammonia level is more than normal -without informed consent

Intervention groups

Patients under the supervision of a physician will undergo a one-year treatment with a ketogenic diet, which includes a ratio of 4 to 1 or 3 to 1 (in children of low age) from fat to carbohydrates plus protein. These patients will be monitored monthly

Main outcome variables

Age, sex, type of treatment; number of seizure attacks; appropriate response to treatment

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20131012014988N5**

Registration date: **2018-05-23, 1397/03/02**

Registration timing: **registered_while_recruiting**

Last update: **2018-05-23, 1397/03/02**

Update count: **0**

Registration date

2018-05-23, 1397/03/02

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

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-04-03, 1396/01/14

Expected recruitment end date

2018-06-21, 1397/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy and complication of ketogenic diet and modified therapy in pediatric's refractory epilepsy ketogenic diet on childhood refractory epilepsy

Public title

Efficacy of ketogenic diet in pediatric's refractory epilepsy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

age : 2 - 15 years lack of seizure control using 2 first line anti epileptic drugs on average 1 attack per month there is no chronic disease such as liver disease or diabetes there is no progressive neurologic disorder parental training informed consent

Exclusion criteria:

liver disease progressive neurologic disorders inborn error of metabolism with ammonia level is more than normal without informed consent

Age

From **2 years** old to **15 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **35**

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

Ethics committee of Tabriz University of Medical Sciences

Street address

Research and Technology Dept, Third Floor, Central Building No. 2, Tabriz University of Medical Sciences, Golghast St.

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Tabriz

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East Azarbaijan

Postal code

5166614766

Approval date

2018-03-05, 1396/12/14

Ethics committee reference number

IR.TBZMED.REC.1396.1108

Health conditions studied

1

Description of health condition studied

types of refractory epilepsy

ICD-10 code

G40

ICD-10 code description

Epilepsy and recurrent seizures

Primary outcomes

1

Description

The response rate to ketogenic diet based on the reduction of seizures

Timepoint

Based on regular monthly follow-up after the start of the ketogenic diet

Method of measurement

questionnaire

2

Description

urine keton body

Timepoint

daily

Method of measurement

urine test tape

Secondary outcomes

1

Description

Quality of life score

Timepoint

Monthly

Method of measurement

questionnaire

Intervention groups

1

Description

Intervention group: Patients undergoing hospitalization and kidney ultrasonography and EEG , initially, are treated with only fluid Equivalent two-thirds of the fluid required in the 24-hour period until the urine ketone is

>= 2+. After that, the diet begins with lipid to a total protein and carbohydrate level of 4 to 1, and patient is discharged from the hospital. After 1 week and then monthly follow up and the rate of reduction in the number of seizures is evaluated and recorded.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Neurology clinic, Children Hospital, Tabriz University Of Medical Sciences

Full name of responsible person

Dr Mohammad Barzegar

Street address

Children Hospital, Sheshghelan Ave, Tabriz, Iran

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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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Web page address

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

Grant name

Grant code / Reference number

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

Yes

Title of funding source

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 Mohammad Barzegar

Position

Pediatric Neurologist, Professor, Faculty Member

Latest degree

Subspecialist

Other areas of specialty/work

Neuroscience

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Dr Mohammad Barzegar

Position

Pediatric Neurologist, Professor, Faculty Member

Latest degree

Subspecialist

Other areas of specialty/work

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Person responsible for updating data

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Full name of responsible person

Dr Bita Poorshiri

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Pediatric Neurology Fellowship

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Other areas of specialty/work

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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