Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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
phrc_mb@tbzmed.ac.ir

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.

City
Tabriz

Province
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
erine 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

City
Tabriz

Province
East Azarbaijan

Postal code
5136735886

Phone
+98 41 3526 2250

Fax
+98 41 3526 2265

Email
phrc_mb@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

City
Tabriz

Province
East Azarbaijan

Postal code
5165665931

Phone
+98 41 3335 7310

Fax
+98 41 3334 4280

Email
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?
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

Street address
Pediatric Health Research Center, Children Hospital, Sheshghelan Street, Tabriz, Iran

City
Tabriz

Province
East Azarbaijan

Postal code
5136735886

Phone
+98 41 3526 2265

Fax
+98 41 3526 2265

Email
phrc_mb@tbzmed.ac.ir

Person responsible for scientific 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

Street address
Pediatric Health Research Center, Children Hospital,

Sheshghelan Street, Tabriz, Iran

City
Tabriz

Province
East Azarbaijan

Postal code
5136735886

Phone
+98 41 3526 2265

Fax
+98 41 3526 2265

Email
phrc_mb@tbzmed.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Tabriz Children Hospital

Full name of responsible person
Dr Bita Poorshiri

Position
Pediatric Neurology Fellowship

Latest degree
Subspecialist

Other areas of specialty/work
Neuroscience

Street address
Pediatric Health Research Center, Children Hospital, Sheshghelan Street, Tabriz, Iran

City
Tabriz

Province
East Azarbaijan

Postal code
5136735886

Phone
+98 41 3526 2265

Fax
+98 41 3526 2265

Email
bpskam@yahoo.com

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