

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

Assesment of ketogenic diet effects on lipid profile in patients with refractory epilepsy.

Protocol summary

Summary

In this study, patients suffering from refractory epilepsy are referred by Child Neurologists to Ketogenic Diet clinic. IN this clinic parents and patients,if possible, are provided with essential information and skills about side effects and advantages of this diet. Provided that testimonial was thoughtfully submitted by parents or caregivers, that they were privileged to treat their child by Ketogenic Diet, laboratory tests should be performed.If there is no contraindication in laboratory results,the patient will be admitted in the hospital to start Ketogenic Diet. The patients are being followed based on specific protocols.Follow-up evaluations include: lipid profiles, liver function tests, urine analysis, kidneys ultrasonography, and echocardiography in determined intervals. In this study, essential laboratory tests are conducted before admission, one month,three months and six months after starting treatment. If there is any critical side effect during treatment, Ketogenic Diet will be stopped promptly. At the end of six-month duration of study, data will be evaluated statistically.The type of regimen is classical and is not changed to other kinds of regimen such as Atkins(if so, the patient will be omitted from study). However our study is over in this stage, but treatment of patients will be observed continuously until the end.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015042021607N2**

Registration date: **2015-07-04, 1394/04/13**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-07-04, 1394/04/13

Registrant information

Name

Parviz Karimi

Name of organization / entity

Tehran University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Investigator

Expected recruitment start date

2015-01-11, 1393/10/21

Expected recruitment end date

2015-07-12, 1394/04/21

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assesment of ketogenic diet effects on lipid profile in patients with refractory epilepsy.

Public title

Assessment of ketogenic diet(KD) on blod lipid in patients with refractory epilepsy.

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:refractory epilepsy ; don't have contraindicated ; Above 2 years old. Exclusion criteria:

inability to continue the ketogenic diet for 6 months.

Age

From **2 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **33**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

In this study, patients suffering from refractory epilepsy are referred to Ketogenic Diet clinic. IN this clinic parents and patients,if possible, are provided with essential information and skills about side effects and advantages of this diet.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran University of Medical Sciences

Street address

Keshavarz Blvd.

City

Tehran

Postal code

1417653761

Approval date

2015-01-10, 1393/10/20

Ethics committee reference number

9211118002-134395

Health conditions studied

1

Description of health condition studied

Refractory Epilepsy

ICD-10 code

G40-G47

ICD-10 code description

Episodic and paroxysmal disorders

Primary outcomes

1

Description

Plasma lipid profil

Timepoint

Before treatment and at three and six month after treatment

Method of measurement

TG; Total Chol; HDL; LDL by mg/dl

Secondary outcomes

1

Description

Effect of KD on seizure control; urin random Ca; Cr; oxalate; uric acid; BLOOD ca; vitD; thyroid function tests; liver function tests; heart failure

Timepoint

Before treatment; 3 mounths; 6 months after treatment

Method of measurement

Seizure control by reduction in numbers of paroxysms; urine random Ca; urine random uric acid urinerandom oxalate; liver function tests; thyroid function tests; serum Ca and vit D by mg/dl; cardiovascular by ejection fraction that measured by litre per min

Intervention groups

1

Description

In this study, patients suffering from refractory seizure are treated with classic KD. This type of treatment is continued according to the required response and tolerance .In Ketogenic Diet, 80 percent of calories are provided from fat and the rest from carbohydrates and proteins.Ketogenic diet has some complications. These complications include: nausea, vomiting, cinstipation, hyperlipidemia, renal stones, and heart failure. The risk of these complications has been not assessed adequately in Iran yet, so we evaluated patients in determined intervals.In this study,patients were followed clinically and by laboratory evaluations before and after treatment ,in tree months, six months, and 12months intervals

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Chidren's Medical Centr Hospital

Full name of responsible person

professor Mahmood Mohamadi

Street address

Chidren's Medical Centr Hospital, Dr. Gharib Street
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of Tehran University of
Medical Sciences

Full name of responsible person

Dr. Yunesian

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Grant name

-

Grant code / Reference number

-

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

Yes

Title of funding source

Vice Chancellor for research of Tehran University of
Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries

Contact**Name of organization / entity**

Chidren's Medical Centr Hospital

Full name of responsible person

Dr.Gholamreza Zamani

Position

Associated professor

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty