

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jun 2026

Clinical trial of the effect of Ketocal formula on the frequency of seizure in 1-5-Year-Old children suffering from Intractable epilepsy to antiepileptic drugs.

Protocol summary

Summary

About 1/3 of the patients suffering from epilepsy cannot be controlled with proper pharmaceutical treatment. Ketogenic diet is an effective treatment for such patients. In this study, we select thirty children aged 1-5 year-old, recognized as intractable epilepsy that fails to respond to drug treatment, who applied to Children's Medical Center in Tehran, during the first six months of the year 2014. Those should be qualified for receiving ketogenic diet, and prescribe them, as outpatients, a kind of ready-made ketogenic diet, called Ketocal Powder for a period of four months. The Ketocal formula will constitute the major daily diet of the patients, and their carbohydrate-content food will be minimized. Blood sampling were done at the beginning and end of intervention for measurement of some parameters, In addition, The ketone content of their urine will be checked daily. Those who can not complete the formula consumption and/or in case of severe complications will be excluded . The patients' formula tolerance, complications, the effect of the Ketocal formula on reduction of seizures will be assessed clinically and also by electroencephalogram twice during the period of study. If this kind of powder proves to be effective, then, it may be prescribed as a proper, ready-made and accessible diet to the patients suffering from intractable epilepsy, leading to reduction in hospitalization and decrease the burden of the illness.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201210016907N5**
Registration date: **2014-06-28, 1393/04/07**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-06-28, 1393/04/07

Registrant information

Name

Mahmoudreza Ashrafi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6612 9252

Email address

ashrafim@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2014-05-27, 1393/03/06

Expected recruitment end date

2014-10-12, 1393/07/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial of the effect of Ketocal formula on the frequency of seizure in 1-5-Year-Old children suffering from Intractable epilepsy to antiepileptic drugs.

Public title

Effect of ketocal formula on the seizure

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Having seizures which are intractable with at least two anti-epileptic medications, and having seizures once in every month, on average, in the last year; having no contraindication in respect of Ketogenic diet based on the reviewed sources. Exclusion criteria: Acute complications due to the treatment, leading to withholding the treatment.

Age

From **12 months** old to **5 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

Tehran University of Medical Sciences

Street address

Sixth floor, Headquarter for Tehran University of Medical Sciences, On the Corner of Keshavarz Blvd. and Qods Street, Keshavarz Blvd., Tehran, Iran

City

Tehran

Postal code

Approval date

2014-05-25, 1393/03/04

Ethics committee reference number

130/496

Health conditions studied

1

Description of health condition studied

Epilepsy

ICD-10 code

G40 Epilep

ICD-10 code description

Episodic and paroxysmal disorders

Primary outcomes

1

Description

Seizure frequency

Timepoint

Before intervention and during intervention

Method of measurement

Average of seizure frequency per week

Secondary outcomes

1

Description

Tolerability to ketocal diet

Timepoint

During intervention

Method of measurement

Descriptive

2

Description

Blood lipid profile(cholesterol, triglyceride, LDL, HDL)

Timepoint

At beginning and end of intervention

Method of measurement

Blood sampling and laboratory measurement

3

Description

Blood calcium

Timepoint

At beginning and end of intervention

Method of measurement

Blood sampling and laboratory measurement

4

Description

Serum vitamin 25 hydroxy vitamin D

Timepoint

At beginning and end of intervention

Method of measurement

Blood sampling and laboratory measurement

5

Description

Side effects

Timepoint

During intervention

Method of measurement

Parents report

6

Description

Serum zinc

Timepoint

At beginning and end of intervention

Method of measurement

Blood sampling and laboratory measurement

7

Description

Blood glucose

Timepoint

At beginning and end of intervention and when the patient feels weakness

Method of measurement

Blood sampling and laboratory measurement and glucometry

8

Description

Blood alkalyn phosphatase

Timepoint

At beginning and end of intervention

Method of measurement

Blood sampling and laboratory measurement

9

Description

Blood urea

Timepoint

At beginning and end of intervention

Method of measurement

Blood sampling and laboratory measurement

10

Description

Plasma creatinine

Timepoint

At beginning and end of intervention

Method of measurement

Blood sampling and laboratory measurement

Intervention groups

1

Description

This intervention is conducted, without control group, and the same patients suffering from intractable epilepsy are studied prior to and after being fed with the Ketocal formula. The volume of the formula will gradually increase until Ketone appears in the urine. Then, the frequency of seizures per week, side effects and tolerability in the four months of prescription of the formula will be assessed. The frequency of seizures are compared with those occurred prior to the commencement of the treatment.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Children's Medical Center, Tehran

Full name of responsible person

Seyed Ahmad Hosseini

Street address

Children's Medical Center, Qarib street, Tehran, Iran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

NUTRICIA

Full name of responsible person

Mojdeh Zohari

Street address

No.10, 6th floor, Negar tower, Negar Alley, Vanak Square

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

NUTRICIA

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

Tehran University of Medical Sciences

Full name of responsible person

Seyed Ahmad Hosseini

Position

Fellowship of pediatrics neurology

Other areas of specialty/work

Street address

Children's Medical Center, Qarib Street, Tehran

City

Tehran
Postal code
Phone
+98 21 6693 5848
Fax
Email
parnianah@yahoo.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Mahmmoud Reza Ashrafi
Position
Pediatrics neurologist, Professor of TUMS
Other areas of specialty/work
Street address
Children's Medical Center, Qarib street, Tehran
City
Tehran
Postal code
Phone
+98 21 6693 5848
Fax
Email
mr_ashrafi@yahoo.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Seyed Ahamd Hosseini
Position
Fellowship of pediatrics neurology
Other areas of specialty/work
Street address
Children's Medical Center, Qarib street, Tehran
City
Tehran
Postal code
Phone
+98 21 6693 5848
Fax
Email
Web page address

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