

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jun 2026

Evaluation the effect of Modified Atkins diet in controlling refractory epilepsy in adult patients and comparing with adult epileptic patients without using this diet: a controlled randomized clinical trial

Protocol summary

Summary

We will aim to conduct a controlled randomized clinical trial to evaluate the efficacy of modify Atkin diet in adult with refractory epilepsy between patinets using and not using modify Adkin diet. The inclusion criteria were the age of ≥ 18 years and refractory epilepsy (two or more seizures attacks every month in spite of treatment with at least two appropriate antiepileptic drugs). Adults with hypercholesterolemia, cardiovascular, or renal disease will exclude. Patients significantly underweight (body mass index < 18.5), with status epilepticus within the past 6 months, or nonepileptic seizures will also exclude from participation. We will enroll 60 refractory adult epileptic cases. time of intervention will be two months. The primary outcome will be at least 50% decrease in seizure frequency

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138803051949N1**

Registration date: **2013-02-09, 1391/11/21**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2013-02-09, 1391/11/21

Registrant information

Name

Mohammad Zare

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Isfahan University of Medical Science

Expected recruitment start date

2010-01-01, 1388/10/11

Expected recruitment end date

2012-12-31, 1391/10/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation the effect of Modified Atkins diet in controlling refractory epilepsy in adult patients and comparing with adult epileptic patients without using this diet: a controlled randomized clinical trial

Public title

Comparison the effect of Modified Atkins diet in decreasing frequency of seizure in adult patients with refractory epilepsy with using Modified Atkins diet and patients with refractory epilepsy control without using Modified Atkins diet group.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: > 18 years; taking at least two types of anticonvulsants; at least have monthly seizures.

Exclusion Criteria: Adults with hypercholesterolemi, cardiovascular, renal disease; patients significantly

underweight (body mass index < 18.5); status epilepticus within the past 6 months; nonepileptic seizures

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Isfahan University of Medical Sciences

Street address

Isfahan University of Medical Sciences, Isfahan

City

Isfahan

Postal code

Approval date

2009-01-20, 1387/11/01

Ethics committee reference number

388085

Health conditions studied

1

Description of health condition studied

epilepsy

ICD-10 code

G40

ICD-10 code description

Localization-related (focal)(partial) idiopathic epilepsy and epileptic syndromes with seizures of localized onset

Primary outcomes

1

Description

decrease of 50% number of seizure attack

Timepoint

In the first day and every 4 weeks till two months

Method of measurement

history

Secondary outcomes

1

Description

Increase of ketone body

Timepoint

weekly

Method of measurement

urinary dipstick

Intervention groups

1

Description

1- Case group: Modify Atkin's diet (Less than 15 gr carbohydrate/day in diet) for two months

Category

Lifestyle

2

Description

2- Control group: No diet

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra hospital

Full name of responsible person

Dr Ali Asghar Okhovat Souraki

Street address

Isfahan -soffe Ave-alzahra hospital

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Isfahan University of Medical Sciences

Full name of responsible person

Dr Taleb Azarm

Street address

Isfahan University of Medical Sciences

City
Isfahan

Grant name

Grant code / Reference number

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

Title of funding source
Isfahan 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
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Associate Proffesor of Neurology

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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