Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Study the prevalence of celiac in epilepsy patients and effect of gluten-free diet in controlling the seizureof the patients

Protocol summary

Summary

Study population are 333 patients with Epilepsy referred from Neurology Clinic of Imam Reza Hospital and Farabi Hospital to Gastroenterology Clinic. At first, patients will be screened for celiac with anti-tTG laboratory test and duodenal biopsy will be performed in positive test patients for final approval. They will be randomly divided into two groups. All of patients will be monitored continuously for 3 months and frequency and duration of seizures will be recorded. Group A (intervention) will receive a gluten-free diet to treat celiac disease and group B (control) will continue normal diet. Patients will be visited monthly till 5 months and frequency and duration of seizures will be recorded.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201108097271N1**
Registration date: **2011-09-01, 1390/06/10**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2011-09-01, 1390/06/10

Registrant information

Name
Nosratollah Babaii
Name of organization / entity
Kermanshah Univercity of Medical Scinces
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Iran (Islamic Republic of)
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+98 83 1427 6302
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nbabaii@kums.ac.ir

Recruitment status

Recruitment complete

Funding source

Kermanshah univercity of medical scinces

Expected recruitment start date

2011-06-14, 1390/03/24

Expected recruitment end date

2012-12-14, 1391/09/24

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study the prevalence of celiac in epilepsy patients and effect of gluten-free diet in controlling the seizureof the patients

Public title

Study of celiac frequency in epileptic patient and influnce of celiac treatment on treatment of epilepsy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Epilepsy and getting experience at least one seizure per month during the past six months; confirmed celiac disease with a positive tTG test and duodenal biopsy. Exclusion criteria: Changing the type or dose of anticonvulsant drug in the study period.

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **333**

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

Kermanshah university of medical sciences and health services

Street address

Kermanshah university of medical sciences and health services, Shahid beheshti Blvd

City

kermanshah

Postal code

6714858743

Approval date

2011-06-14, 1390/03/24

Ethics committee reference number

12533

Health conditions studied

1

Description of health condition studied

epilepsy

ICD-10 code

G40

ICD-10 code description

epilepsy

2

Description of health condition studied

celiac

ICD-10 code

K90.0

ICD-10 code description

Coeliac disease

Primary outcomes

1

Description

seizure

Timepoint

monthly till 5 month after begining of intervention

Method of measurement

seizures frequency and duration of each seizure

Secondary outcomes

empty

Intervention groups

1

Description

control group: no intervention

Category

N/A

2

Description

intervention group: gluten-free diet

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Neurology Clinic of Imam Reza Hospital and Farabi Hospital Kermanshah.

Full name of responsible person

Dr Nosratollah Babai

Street address

City

Kermanshah

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah university of medical sciences and health services

Full name of responsible person

Dr Fraid Njafi

Street address

Kermanshah university of medical sciences and health services, Shahid beheshti Blvd

City

Kermanshah

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Kermanshah university of medical sciences and health services

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

Kermanshah university of medical sciences and health services.

Full name of responsible person

Dr Nosratollah Babai

Position

Resident f inernal medicine

Other areas of specialty/work

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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