

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The Evaluation of Relationship between Food Allergy and Refractory Seizures in Children

Protocol summary

Study aim

Evaluation of Relationship between Food Allergy and Refractory Seizures in Children

Design

In This study 34 Patients with Inclusion Criteria referred to Neurologic Clinic and no response to Opimal anti epileptic drugs came to allergy clinic; each of Patient had a Specific Code

Settings and conduct

This Study was conducted Clinical Trial.34 Patients with Inclusion Criteria referred to Neurologic Clinic and no Response to Opimal Anti epileptic Drugs came to Allergy Clinic; Demographic Data, the Daily Seizures Frequency, Eosinophilia, Serum IgE, Type of Seizure, MRI and EEG and Skin Prick Tests finding with Indoor, Outdoor and Food Allergens of Patients entered in Forms.Before and After 8-weeks Food avoidance with 6 Main Food, Daily Seizures Frequency was recorded in the Patient Information Form.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: The Patients Should have Refractory Idoipatic Seizures. Minimum Age is 1 month and Maximum Age is 16 years Exclusion Criteria: Not able to do food avoidance Certain Cause for Seizure like Cerebral Palsy

Intervention groups

34 Patients 1month to 16 years old with Refractory Seizures referred to Neurologic Clinic and no Response to Optimal anti Epileptic Drugs came to Allergy Clinic Skin Prick Tests Finding with Indoor, Outdoor and Food Allergens of Patients entered in Forms.

Main outcome variables

Reduction in Seizure Frequency Food Regimen Tolerance Lack of Complications

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171022036925N2**

Registration date: **2018-03-10, 1396/12/19**

Registration timing: **retrospective**

Last update: **2018-03-10, 1396/12/19**

Update count: **0**

Registration date

2018-03-10, 1396/12/19

Registrant information

Name

Hoshng Gorjipour

Name of organization / entity

Mofid children's hospital

Country

Iran (Islamic Republic of)

Phone

+98 22227021

Email address

info-mch@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Children neurologic research center

Expected recruitment start date

2016-06-21, 1395/04/01

Expected recruitment end date

2017-02-18, 1395/11/30

Actual recruitment start date

2016-07-22, 1395/05/01

Actual recruitment end date

2017-03-18, 1395/12/28

Trial completion date

empty

Scientific title

The Evaluation of Relationship between Food Allergy and Refractory Seizures in Children

Public title

Food Allergy and Refractory Seizures in Children

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

The Patients Should have Refractory Idoipatic Seizures
Minimum Age is 1 month and Maximum age is 16 years

Exclusion criteria:

Not able to do Food Avoidance There was certain cause
for Seizure such as Cerebral Palsy Age less than 1 month
and more than 16 years

Age

From **1 month** old to **16 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **36**

Actual sample size reached: **34**

Randomization (investigator's opinion)

N/A

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description

In this study 34 patients 1 month to 16 years old with
refractory seizures referred to neurologic clinic that
received optimal epilepsy drugs came to our allergy
clinic for this intervention

Placebo

Not used

Assignment

Single

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Shahid Beheshti University of Medical Sciences

Street address

Velenjak-University Bulvar

City

Tehran

Province

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Postal code

1985717443

Approval date

2016-05-29, 1395/03/09

Ethics committee reference number

IR.SBMU.RETECH.REC.1395.167

2**Ethics committee****Name of ethics committee**

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Street address

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Province

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Postal code

1985717443

Approval date

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Health conditions studied**1****Description of health condition studied**

Refractory Seizures

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Seizure

Timepoint

Before and 8 Weeke After Intervention

Method of measurement

Seizure Frequency in Day-Week and Month

Secondary outcomes**1****Description**

Seizure Frequency

Timepoint

Daily-Weekly-Monthly

Method of measurement

Seizure Frequency in Day-Week-Month

Intervention groups**1****Description**

Six Main Food Avoidance((Milk-Egg-Peanut-Wheat-Soya-
Sea Food1-Six Main Food Avoidance(Milk- Egg-Peanut-
Wheat-Soya-Sea Food)2-Use Neocate Formula or
Elemental Base Formula

Category
Lifestyle

Type of organization providing the funding
Academic

Recruitment centers

1

Recruitment center

Name of recruitment center
Mofid Children's Hospital
Full name of responsible person
Hoshang Gorjipour
Street address
Shareeati Street, Near to Mirdamad
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1546815514
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info-mch@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Pediatric Neurologic Research Center
Full name of responsible person
Dr Mohammad Ghofrani
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1546815514
Phone
+98 21 2290 9559
Email
pnr.center@sbmu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Pediatric Neurologic Research Center
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

Person responsible for general inquiries

Contact

Name of organization / entity
Mofid Children's Hospital
Full name of responsible person
Hoshang Gorjipour
Position
Fellow of Immunology and Allergy
Latest degree
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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

Contact

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00
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dr.hgorjipour@gmail.com

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

After Registration in Validate Journals

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not 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

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available