

# 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**

Tehran

**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**

Shahid Beheshti University of Medical Sciences

**Street address**

Velenjak-University Bulvar

**City**

Tehran

**Province**

Tehran

**Postal code**

1985717443

**Approval date**

2016-05-29, 1395/03/09

**Ethics committee reference number**

IR.SBMU.RETECH.REC.1395.167

**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  
**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
1546815514  
**Phone**  
+98 21 2222 7021  
**Email**  
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  
**Street address**  
Mofid Children's Hospital  
**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
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**  
Subspecialist  
**Other areas of specialty/work**  
**Street address**  
Mofid's Hospital  
**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
1546815514  
**Phone**  
+98 21 2284 4186  
**Fax**  
**Email**  
dr.hgorjipour@ymail.com  
**Web page address**

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Mofid Children's Hospital  
**Full name of responsible person**  
Dr Mahbubeh Mansoori  
**Position**  
Immunologist and Allergist  
**Latest degree**  
Subspecialist  
**Other areas of specialty/work**  
**Street address**  
Mofid's Hospital  
**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
1546815514  
**Phone**  
+98 21 2222 7021  
**Fax**  
**Email**  
mbmans65@gmail.com  
**Web page address**

## Person responsible for updating data

### Contact

**Name of organization / entity**

Mofid Children's Hospital  
**Full name of responsible person**  
Hoshang Gorjipour  
**Position**  
Fellow of Immunology and Allergy  
**Latest degree**  
Subspecialist  
**Other areas of specialty/work**  
**Street address**  
Shareeati Street, Near to Mirdamad  
**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
1546815514  
**Phone**  
00  
**Fax**  
**Email**  
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