Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparative study of the effect of diazepam suppositories and oral diazepam in the prophylaxis of febrile seizures in children referred to Amir Kabir Hospital of Neurology in 2016

Protocol summary

Summary

Aim of this study Comparative study of the effect of Diazepam suppositories and oral Diazepam in the prophylaxis of febrile seizures in children referred to neurology clinic in Amir Kabir Hospital in 2016.This study is clinical trials and double blind. We will divide children 6 months to 60 months with febrile seizures referred to neurology clinic in Amir Kabir Hospital in two groups. We treat patients by 0.3 milligram in kilogram Oral Diazepam TDS in start of febrile to control febrile in first group. We treat patients by 0.5 milligram in kilogram Suppository Diazepam TDS in start of febrile to control febrile in second group.We will record number of frequent of febrile seizures in duration of treatment after one years. Inclusion criteria: 6 months to 60 months with febrile seizures Exclusion criteria: seizures with metabolic causes; seizures with central nervous system causes

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017070320258N50**
Registration date: **2017-07-06, 1396/04/15**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-07-06, 1396/04/15

Registrant information

Name

Fariba Farokhi

Name of organization / entity

Arak University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 86 3222 2003

Email address

f.farokhi@arakmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor and Research,Arak University of Medical Sciences

Expected recruitment start date

2016-02-19, 1394/11/30

Expected recruitment end date

2018-02-19, 1396/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative study of the effect of diazepam suppositories and oral diazepam in the prophylaxis of febrile seizures in children referred to Amir Kabir Hospital of Neurology in 2016

Public title

Comparative study of the effect of diazepam suppositories and oral diazepam in the prophylaxis of febrile seizures in children referred to Amir Kabir Hospital of Neurology in 2016

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 6 months to 60 months with febrile seizures Exclusion criteria: seizures with metabolic

causes; seizures with central nervous system causes

Age

From **6 months** old to **5 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **212**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee Arak University Of Medical Sciences

Street address

Dr Mohammad Rafiei, Vice chancellor for research, Payambar azam complex, Basij squre, Sardasht, Arak

City

Arak

Postal code

38149578558

Approval date

2016-02-15, 1394/11/26

Ethics committee reference number

IR.ARAKMU.REC.1394.303

Health conditions studied

1

Description of health condition studied

febrile seizures

ICD-10 code

R56.0

ICD-10 code description

Febrile convulsions

Primary outcomes

1

Description

febrile seizures

Timepoint

before treatment and end of one years

Method of measurement

Number times of incidence

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: We treat patients by 0.3 milligram in kilogram Oral Diazepam TDS in start of febrile to control febrile in first group.

Category

Prevention

2

Description

Intervention group: We treat patients by 0.5 milligram in kilogram Suppository Diazepam TDS in start of febrile to control febrile in second group.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Amirkabir hospital

Full name of responsible person

Dr Shariatmadari

Street address

Amirkabir hospital, Parastar square, Arak

City

Arak

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Arak University of Medical Sciences

Full name of responsible person

Dr Mohammad Rafiee

Street address

Vice chancellor for research, Payambar Azam Complex, Basij square, Sardasht, Arak

City

Arak

Grant name
-
Grant code / Reference number
-
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research, Arak 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
Amirkabir hospital
Full name of responsible person
Dr Shariatmadari
Position
Faculty member, Pediatric pediatrician
Other areas of specialty/work
Street address
Amirkabir hospital, Parastar square
City
Arak
Postal code
3814957558
Phone
+98 86 3222 2003
Fax
+98 863222003
Email
alish9270@gmail.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Dr Shariatmadari
Position
Faculty member
Other areas of specialty/work
Street address
Amirkabir hospital,Parastar squre
City
Arak
Postal code
3814957558
Phone
+98 86 3222 2003
Fax
+98 863222003
Email
alish9270@gmail.com
Web page address
-

Person responsible for updating data

Contact
Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Ali Shariati
Position
medicine student
Other areas of specialty/work
Street address
Payambar Azam Complex, Basij Square, Sardasht, Arak
City
Arak
Postal code
3814957558
Phone
+98 86 3222 2003
Fax
+98 863222003
Email
alish9270@gmail.com
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