

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison the effectiveness of diazepam and phenobarbital for prevention of recurrent seizure In early stages of febrile convulsion in children 6 month to 5 years

Protocol summary

Summary

The aim of this study is to compare the effectiveness of 3 interventions for prevention of recurrence in early stages of febrile seizures in children under 5 years. This study will determine whether these interventions or no intervention are different during the course of the disease? In addition, the mentioned interventions are accompanied with what kind of side effects. In this study all of the patients who are qualified to include in the research will be included gradually in the study. In based on block randomization. Group 1: the patients who won't receive any drug of seizure. Group 2: the patients will receive phenobarbital stat 10 mg/kg IM at the beginning of the admit. Group 3: the patients will receive phenobarbital stat 10mg/kg IM at the beginning of the admit and then 2.5 mg/kg/dose IM every 12 hours and this process will be followed by receiving tab phenobarbital with the same dose after the beginning of oral nutrition until cut fever. Group 4: the patients will receive tab diazepam 0/3 mg/kg in every 8 hours and this process will be continued until cut fever. If one of the mentioned group will strike recurrent seizure during the period of admit in the hospital regardless of the above groups they will receive amp phenobarbital 10 mg/kg IM STAT and 2/5 mg/kg/dose every 12 hours and this process will be followed by receiving tab phenobarbital with the same dose after the beginning of oral nutrition. the patient information will be recorded as recurrent seizure. all of the patients will be checked for the reason of fever. the LP will be accomplished according to circumstance and regarding to the available indication about the reason of the fever. for all of the patients if the temperature of the axillary will be more than 37/5 C. According to circumstance the syrup acetaminophen 10-15 mg/kg oral will be prescribed. regarding to the patient conditions the patient will be requested to do routine tests. in the cases such as complex febrile seizure

or the history of developmental delay or neurological exam the patients are requested to do brain CT scan or brain MRI. All of the information including of the personal information family history the seizure characteristic and recurrency of seizure will be recorded in the information form and the results will be evaluated using SPSS 16 software.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016080229171N1**

Registration date: **2017-02-17, 1395/11/29**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-02-17, 1395/11/29

Registrant information

Name

Afshin Fayazi

Name of organization / entity

Hamedan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 1446 3975

Email address

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Recruitment status

Recruitment complete

Funding source

no

Expected recruitment start date

2015-09-23, 1394/07/01
Expected recruitment end date
2016-09-22, 1395/07/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison the effectiveness of diazepam and phenobarbital for prevention of recurrent seizure In early stages of febrile convulsion in children 6 month to 5 years

Public title
Effectiveness of diazepam and phenobarbital in prevention of recurrent febrile seizure

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:First Simple febrile convulsion; complex febrile convulsion(maximum two); recurrent febrile convulsion(maximum one); temperature of more than 37/5 axillary during of seizure; no history of seizure without having fever; lack of the previous neurodevelopmental delay; age of more than 6 months to 5 years. exclusion criteria: status epilepticus; electrolyte imbalance; serial seizure before referring to hospital(more than two); abnormality in neuroimaging; drug reaction to phenobarbital(skin rash, Steven Johnson, TEN), noncooperation; serial seizure more as 2

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

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **200**

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
Hamedan University Of Medical Sciences
Street address
Ayatollah Kashani Boulevard, Khaje Rashid Crossroad
City
Hamedan
Postal code
Approval date
2016-05-14, 1395/02/25
Ethics committee reference number
IR.UMSHA.REC.1395.88

Health conditions studied

1
Description of health condition studied
febrile convulsions
ICD-10 code
R56.0
ICD-10 code description
Febrile Convulsions

Primary outcomes

1
Description
Reccurency of seizure
Timepoint
in admit hospital
Method of measurement
questionar

2
Description
Status Epilepticus
Timepoint
in admit hospital
Method of measurement
Questionar

Secondary outcomes

empty

Intervention groups

1
Description
IN 3 interventions groups, first group amp phenobarbital 10mg/kg stat
Category
Treatment - Drugs

2

Description

No drug in control group

Category

Treatment - Drugs

3

Description

Amp Phenobarbital 10mg/kg stat IM and then 2.5 mg/kg/dose IM every 12 hours to cut fever

Category

Treatment - Drugs

4

Description

Tab Diazepam 0/3 mg/kg in 8 hour to cut fever

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Besat Hospital

Full name of responsible person

Reihane Eslamian

Street address

Besat hospital, Ayatollah Motahari Boulevard, Resalat Square

City

Hamedan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University Of Medical Sciences

Full name of responsible person

Hashemian Farnaz

Street address

Ayatollah kashani Boulevard, Khaje Rashid Crossroad

City

Hamedan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Hamedan 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

Hamedan University Of Medical Sciences

Full name of responsible person

Afshin Fayazi

Position

Pediatrics Neurologist

Other areas of specialty/work

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Other areas of specialty/work

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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