Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison the effectiveness of diazepam and phenobarbital for prevention of recurrent seizure In early stages of febrile convalsion 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 caracteristic 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)
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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 convalsion 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); reccurent 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 inneuroimaging; drug reaction to phenobarbital(skin rash,stiven janson,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 Boulvard, 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 Boulvard, 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
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Ayatollah kashani Boulvard,Khaje Rashid Crossroad
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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
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Afshin Fayazi
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Reihane Eslamian
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Pediatric Assistent

Other areas of specialty/work

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Postal code

Phone

00

Fax

Email

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