

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Comparison of the therapeutic effect of parenteral Phenobarbital and oral Diazepam on recurrency of febrile seizure in hospitalized children- A randomized controlled clinical trial

Protocol summary

Study aim

Comparison of the therapeutic effect of parenteral Phenobarbital and oral Diazepam on recurrency of febrile seizure in hospitalized children

Design

Clinical trial with control group, with parallel groups, no blinding, randomized, phase 3 on 90 patients. Sealed envelope software is used for randomization

Settings and conduct

This research will be performed on children aged 6 months to 6 years in 17 Shahrivar Hospital of Rasht for one year. After selecting the children, written consent will be obtained from the parents. Will be registered. Randomization before the program will be done by considering 30 people in each group in 6 blocks and each of them in a separate envelope according to the list obtained from the software. The software is placed and closed in it and will be given to the third person. If the patient visits and is eligible, the envelope is opened and treated according to the desired sequence without knowing the next treatment. Group A will receive intravenous phenobarbital, group B will receive oral diazepam, and group C will be controlled, and the patient is unaware of the type of treatment

Participants/Inclusion and exclusion criteria

Inclusion criteria: Parents' satisfaction with the presence of children in the study, children aged 6 months to 6 years and experience the first febrile seizure
Non-entry criteria: Any neurological disease, history of previous seizures and febrile seizures, electrolyte imbalance associated with chronic disease

Intervention groups

1. Intravenous phenobarbital with dosage of 3 to 5 milligram per kilogram per day divided into 2 doses and prescribed for 3 days at the time of hospitalization
2. Oral diazepam at a dose of 33 milligram per kilogram 3 times a

day for 3 days in presence of fever is prescribed
3. The control group does not receive drugs

Main outcome variables

Recurrence of febrile seizure

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200608047689N2**

Registration date: **2021-02-04, 1399/11/16**

Registration timing: **registered_while_recruiting**

Last update: **2021-02-04, 1399/11/16**

Update count: **0**

Registration date

2021-02-04, 1399/11/16

Registrant information

Name

Elham Bidabadi

Name of organization / entity

Guilan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 13 3372 9104

Email address

bidabadi@mail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-01-27, 1399/11/08

Expected recruitment end date

2021-06-22, 1400/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the therapeutic effect of parenteral Phenobarbital and oral Diazepam on recurrency of febrile seizure in hospitalized children- A randomized controlled clinical trial

Public title

Comparison of the therapeutic effect of Diazepam and Phenobarbital in recurrence of febrile seizure

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Parents complete satisfaction with the children's presence in the study Children who experience febrile seizure for the first time

Exclusion criteria:

History of any neurological disease Children with previous history of seizure and febrile seizure Imbalance of electrolytes associated with chronic disease

AgeFrom **6 months** old to **6 years** old**Gender**

Both

Phase

3

Groups that have been masked*No information***Sample size**Target sample size: **90****Randomization (investigator's opinion)**

Randomized

Randomization description

Randomization will be done before the start of the program by <https://www.sealedenvelope.com> considering 30 people in each group (3 groups of Diazepam, Phenobarbital, and control in 2 simple and complex strata) in 6 blocks. Any of them is placed in a separate envelope according to the list obtained from the software and it will be closed and provided to the third person. Patients names will be registered by admission. If the patient comes and is qualified, the envelope will be opened and based on the expected sequence, he/she will be treated.

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**

Ethics committee of the vice chancellor of Guilan University of Medical Sciences

Street address

Siadati street

City

Rasht

Province

Guilan

Postal code

4144444444

Approval date

2021-01-27, 1399/11/08

Ethics committee reference number

IR.GUMS.REC.1399.551

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

Febrile seizure

ICD-10 code

R56.0

ICD-10 code description

Febrile convulsions

Primary outcomes**1****Description**

Recurrence of febrile seizure

Timepoint

The initial outcome will be measured during three days of hospitalization

Method of measurement

The occurrence of any types of seizure

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

The side effects of the drugs such as lethargy, rash and irritability

Timepoint

In 3 days during hospitalization

Method of measurement

The occurrence of complications

Intervention groups

1

Description

Intervention group: 1. Intravenous Phenobarbital at a dose of 3 to 5 milligrams per kilogram per day will be divided into two doses that will be administered daily for 3 days at the time of hospitalization. (Phenobarbital is a Barbiturate and from Chemidarou company with 200 milligrams/1 milliliter ampules.)

Category

Treatment - Drugs

2

Description

Intervention group: 2. Oral Diazepam at a dose of 33 milligrams per kilogram three times a day for three days during fever. (Diazepam is a Benzodiazepine and from Chemidarou company with 2 milligrams tablets.)

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

17 Shahrivar Children's Hospital

Full name of responsible person

Elham Bidabadi

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Siadati Street

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4144654679

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+98 13 3336 9061

Email

bidabadi@mail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rasht University of Medical Sciences

Full name of responsible person

Mohammadreza Naghipour

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Siadati Street

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research@gums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Rasht University of Medical Sciences

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

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Rasht University of Medical Sciences

Full name of responsible person

Elham Bidabadi

Position

Associate Professor

Latest degree

Subspecialist

Other areas of specialty/work

Neurology

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Person responsible for scientific inquiries

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Name of organization / entity

Rasht University of Medical Sciences

Full name of responsible person

Elham Bidabadi

Position

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Latest degree

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Person responsible for updating data**Contact****Name of organization / entity**

Rasht University of Medical Sciences

Full name of responsible person

Elham Bidabadi

Position

Associate Professor

Latest degree

Subspecialist

Other areas of specialty/work

Neurology

Street 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

Regarding the ethical issues and confidentiality

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

No - There is not 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