Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison between Phenobarbital and Topiramate in prevention of relapse of febrile seizure in patients aged 6months to 5 years suffering from Febrile Convulsion

Protocol summary

Summary

The purpose of this study is to compare the effects of phenobarbital and topiramate in the prevention of relapse of febrile convulsion. Patients who have febrile convulsion and haven't received prophylaxis treatment and there is no evidence of metabolic or infectious cause for the convulsion are included in the study. The population under study is from 6 months to 5 years old suffering from febrile convulsion. Among these, 140 patients have been selected and have randomly been divided into two equal groups. The first group takes 5 mg per kg oral phenobarbital in two divided doses per day and the second group takes 5 mg per kg oral Topiramate per day for a year. To ensure proper use of the drug, the patient is asked to visit the clinic again after 1, 2, and 6 months from the first visit to be evaluated. After one year of treatment, patients in both groups are re-examined and after the assessment of the relapse of febrile convulsion, the data is recorded.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013120710087N3**
Registration date: **2014-05-09, 1393/02/19**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2014-05-09, 1393/02/19

Registrant information

Name

Ali Khajeh

Name of organization / entity

Zahedan University Of Medical Science

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice-Chancellery of Research and Technology zahedan university of medical science

Expected recruitment start date

2011-12-11, 1390/09/20

Expected recruitment end date

2014-07-23, 1393/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison between Phenobarbital and Topiramate in prevention of relapse of febrile seizure in patients aged 6months to 5 years suffering from Febrile Convulsion

Public title

Comparison between Phenobarbital and Topiramate in prevention of relapse of febrile seizure in patients aged 6months to 5 years suffering from Febrile Convulsion

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patients aged 6 months to 5 years suffering from febrile convulsion; if the first febrile convulsion occurs under 1 year of age; positive family

history of febrile convulsion in first-degree relatives; low grade fever during the first attack (less than 39 °C); short period of time between the onset of fever and convulsion; multiple attacks of seizure; if the first febrile convulsion is complex. Exclusion criteria: patients who have clinical or radiographic signs due to chronic mental disease (MR); patients who were diagnosed with meningitis considering the LP; patients whose seizure caused by electrolyte imbalance; history of a seizure without high temperature; patients who received prophylaxis treatment; patients who developed side effect due to receiving Topiramate.

Age
From **1 year** old to **5 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **140**

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
Zahedan University of Medical Science

Street address
Dr Hesabi square

City
Zahedan

Postal code

Approval date
2011-06-13, 1390/03/23

Ethics committee reference number
91-706

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
Decreasing the relapse of Febrile Convulsion

Timepoint
After one year

Method of measurement
Clinical assessment

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group : The patients in the intervention group take 5 mg per kg oral Topiramate per day for a year. To ensure proper use of the drug, the patient is asked to visit the clinic again after 1, 2, and 6 months from the first visit to be evaluated. Patient who cant tolerate the drug due to side effects are excluded from the study. After one year of treatment, patients in both groups are re-examined and after the assessment of the relapse of febrile convulsion, the data is recorded.

Category
Treatment - Drugs

2

Description
Control group: The patients in the control group take 5 mg per kg oral phenobarbital in two divided doses per day for a year. To ensure proper use of the drug, the patient is asked to visit the clinic again after 1, 2, and 6 months from the first visit to be evaluated. Patient who cant tolerate the drug due to side effects are excluded from the study. After one year of treatment, patients in both groups are re-examined and after the assessment of the relapse of febrile convulsion, the data is recorded.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Ali Ebne Abitaleb Hospital

Full name of responsible person
Dr Ali Khaje (assistent professor, Specialty of pediatric neurology)

Street address
Khalij'e Fars highway- Ali Ebne Abitaleb Hospital
City
Zahedan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Zahedan University of Medical Sciense
Full name of responsible person
Vice-Chancellery of Research and Technology of zahedan university of medical sciense
Street address
Dr Hesabi Square
City
Zahedan
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Zahedan University of Medical Sciense
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
Zahedan University of Medical Science
Full name of responsible person
Dr Ali Khaje
Position
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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