

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jul 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)

Phone

+54 13220316

Email address

khajeha@zaums.ac.ir

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 Science

Full name of responsible personVice-Chancellery of Research and Technology of
zahedan university of medical science**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 Science

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

Specialty of Pediatric Neurology

Other areas of specialty/work**Street address**

Ali Ebne Abitaleb Hospital

City

Zahedan

Postal code**Phone**

+98 54 1341 1260

Fax**Email**

khajeha@zaums.ac.ir

Web page address**Person responsible for scientific****inquiries****Contact****Name of organization / entity**

Zahedan University of Medical Science

Full name of responsible person

Dr Ali Khaje

Position

Specialty of Pediatric Neurology

Other areas of specialty/work**Street address**

Ali Ebne Abitaleb Hospital

City

Zahedan

Postal code**Phone**

+98 54 1341 1260

Fax**Email**

khajeha@zaums.ac.ir

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

Zahedan University of Medical Science

Full name of responsible person

Dr Ali Khaje

Position

Specialty of Pediatric Neurology

Other areas of specialty/work**Street address**

Ali Ebne Abitaleb Hospital

City

Zahedan

Postal code**Phone**

+98 54 1242 1638

Fax**Email**

khajea@zaums.ac.ir

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*