

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jul 2026

Comparison of efficacy of Topiramate and Nitrazepam in infantile spasms treatment

Protocol summary

Summary

Infantile spasms are poor prognosis epileptic syndrome. The purpose of this study was to compare clinical efficacy and safety of Topiramate and Nitrazepam in the treatment of infantile spasm. In a randomized clinical trial, 50 children with infantile spasms, aged 2 months to 2 years who are not receiving anticonvulsant treatment will be assigned to receive either Topiramate, 3-12 mg/kg/day or Nitrazepam, 0.5-1 mg/kg/day for two months. Frequency of seizure attacks and adverse effects will be compared between two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138808052639N1**
Registration date: **2009-12-12, 1388/09/21**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2009-12-12, 1388/09/21

Registrant information

Name

Razieh Fallah

Name of organization / entity

Shahid Sadoughi University of Medical Sciences, Yazd,
Iran

Country

Iran (Islamic Republic of)

Phone

+98 35 3822 4000

Email address

fallah@ssu.ac.ir

Recruitment status

Recruitment complete

Funding source

Shaheed Sadoughi University of Medical Sciences, Yazd

Expected recruitment start date

2008-09-22, 1387/07/01

Expected recruitment end date

2010-05-22, 1389/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of efficacy of Topiramate and Nitrazepam in infantile spasms treatment

Public title

Comparison of efficacy of Topiramate and Nitrazepam in infantile spasms treatment

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria : Age range : 2 months to 2 years, presence of infantile spasms , Exclusion criteria : Low compliance, hard to follow up, receiving anticonvulsant drugs

Age

To 2 years old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Faculty of Medicine ethics committee, Shaheed
Sadoughi University of Medical Sciences,

Street address

Boo ali street, Safaeeh, Yazd

City

Yazd

Postal code

Approval date

2009-10-10, 1388/07/18

Ethics committee reference number

65767/1/17/پ

Health conditions studied

1

Description of health condition studied

Infantile spasms

ICD-10 code

G40.4

ICD-10 code description

Other generalized epilepsy and epileptic syndromes

Primary outcomes

1

Description

Monthly frequency of seizures

Timepoint

Two months before intervention, one and two months
after intervention

Method of measurement

Recording seizure attacks by parents

Secondary outcomes

1

Description

side effects

Timepoint

Every month during the study period

Method of measurement

Recording seizure attacks by parents

Intervention groups

1

Description

Topiramate, oral, 3-12 mg/kg/day for two months

Category

Treatment - Drugs

2

Description

Nitrazepam, oral, 0.5-1 mg/kg/day for two months

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Pediatric neurology clinic of Shaheed Sadoughi
University of Medical Sciences

Full name of responsible person

Dr. Razieh Fallah

Street address

Taleghani Blvd, Yazd

City

Yazd

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shaheed Sadoughi University of Medical Sciences

Full name of responsible person

Dr. Fatemeh Ezoddine

Street address

Yazd

City

Yazd

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shaheed Sadoughi 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***Phone****Fax****Email**

FALLAH@ssu.ac.ir

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

Shaheed Sadoughi University of Medical Sciences

Full name of responsible person

Dr. Razieh Fallah

Position

Assistant Professor, Pediatric Neurologist

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

Shaheed Sadoughi Hospital, Pediatrics Ward

City

Yazd

Postal code**Person responsible for updating data****Contact****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*