Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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, recieving 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 Universuty 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 freuency 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

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
Phone
Fax
Email
FALLAH@ssu.ac.ir
Web page address

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