

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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*