

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

22 Jul 2026

### Evaluation of the effectiveness of topiramate in comparison with acetazolamide in children with external hydrocephalus

#### Protocol summary

##### Study aim

Determination of the efficacy of topiramate in comparison with acetazolamide in mean and standard deviation of infant head circumference with external hydrocephalus

##### Design

A clinical trial study, with parallel groups, randomized into two age-matched groups on 50 infants between 3 and 9 months of age with external hydrocephalus

##### Settings and conduct

The study was performed on 50 infants with external hydrocephalus who referred to Shahid Beheshti Hospital in Kashan and Qom Children and were definitively diagnosed by clinical examination, head circumference measurement and sonography. At first, 2 weeks Given the opportunity and acceleration of growth around infants, if they are abnormal, they will be treated. Patients are divided into two groups. The first group received acetazolamide from Iran Daru Company and the second group received topiramate from Sobhan Company. At the end of each month, the head circumference is measured, and at the end of the 2-month treatment period, patients undergo Brain Sonography. One month after the end of the 2-month drug intervention, patients are evaluated for external hydrocephalus.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria are normal development and criteria for diagnosing external hydrocephalus based on clinical evidence and imaging studies and negation of other major causes of head circumference (no brain tumor, internal hydrocephalus, subdural hematoma and symptoms of increased ICP). Exclusion criteria: having a brain tumor and subdural hematoma, symptoms of increased intracranial pressure, Abnormal cognitive motor development, the presence of internal hydrocephalus

##### Intervention groups

The first group receives acetazolamide from Iran Daru

Company and the second group receives topiramate from Sobhan Company

##### Main outcome variables

Head circumference, motor developmental status, fontanel size, fontanel position, case group

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20201105049278N1**

Registration date: **2021-02-01, 1399/11/13**

Registration timing: **retrospective**

Last update: **2021-02-01, 1399/11/13**

Update count: **0**

##### Registration date

2021-02-01, 1399/11/13

##### Registrant information

##### Name

Hosein Mahmoudzadeh

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 5550 0111

##### Email address

mahmoudzadeh-h@mail.kaums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-09-22, 1399/07/01

##### Expected recruitment end date

2020-11-21, 1399/09/01

##### Actual recruitment start date

empty

**Actual recruitment end date**  
empty

**Trial completion date**  
empty

**Scientific title**  
Evaluation of the effectiveness of topiramate in comparison with acetazolamide in children with external hydrocephalus

**Public title**  
The effectiveness of topiramate in comparison with acetazolamide in children

**Purpose**  
Diagnostic

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
 Being between 3 and 9 months old Final diagnosis of external hydrocephalus based on clinical evidence and brain imaging Normal status of cognitive motor development (based on interview and clinical examination)  
**Exclusion criteria:**  
 Having a brain tumor and subdural hematoma Symptoms of increased intracranial pressure Abnormal cognitive motor development Existence of internal hydrocephalus

**Age**  
From **3 months** old to **9 months** old

**Gender**  
Both

**Phase**  
3

**Groups that have been masked**  
*No information*

**Sample size**  
Target sample size: **50**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
A study on 50 infants with external hydrocephalus who referred to Shahid Beheshti Hospital in Kashan and Qom Children and were randomly divided into 2 groups of 25 blocks. In this method, it was done randomly by flipping the card. In this method, a number of cards or letters selected by the researcher as the first group and the same number of cards for the next groups are considered; Then, by merging the cards together (flipping the cards), a card is taken out and its allocation is recorded. The cards are then merged again and another card is removed. This process continues until a random sequence is reached according to the sample size (25 pieces).

**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

Ethics Committee in Research, School of Medicine and Dentistry, Kashan University of Medical Science

##### Street address

Kashan - Qutb Ravandi Boulevard - Kashan University of Medical Sciences

##### City

Kashan

##### Province

Isfahan

##### Postal code

8715988141

#### Approval date

2020-09-08, 1399/06/18

#### Ethics committee reference number

IR.KAUMS.MEDNT.REC.1399.094

## Health conditions studied

### 1

#### Description of health condition studied

External hydrocephalus

#### ICD-10 code

G91.9

#### ICD-10 code description

Hydrocephalus, unspecified

## Primary outcomes

### 1

#### Description

External hydrocephalus

#### Timepoint

At the end of each month, the head circumference is measured and at the end of the 2-month treatment period, patients undergo Brain Sonography, and one month after the end of the 2-month drug intervention, patients are evaluated for external hydrocephalus.

#### Method of measurement

Brain Sonography

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: Intervention group: Acetazolamide

from Iran Daroo Company (receiving 20 mg per kg of infant weight daily in two divided doses for 2 months)

**Category**

Treatment - Drugs

**2**

**Description**

Intervention group: Intervention group: Topiramate from Sobhan Company (receiving topiramate at the rate of 5 mg per kg body weight of the infant daily and in two divided doses for 2 months)

**Category**

Treatment - Drugs

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Shahid Beheshti Hospital, Kashan

**Full name of responsible person**

Hosein Mahmoudzadeh

**Street address**

Kashan - Qutb Ravandi Boulevard - Kashan University of Medical Sciences

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**Postal code**

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mahmoudzadeh-h@mail.kaums.ac.ir

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Kashan University of Medical Sciences

**Full name of responsible person**

Ahmad Talebian

**Street address**

Kashan - Qutb Ravandi Boulevard - Kashan University of Medical Sciences

**City**

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Isfahan

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mahmoudzadeh-h@mail.kaums.ac.ir

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Kashan University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

Public

**Domestic or foreign origin**

Domestic

**Category of foreign source of funding**

empty

**Country of origin**

**Type of organization providing the funding**

Academic

**Person responsible for general inquiries**

**Contact**

**Name of organization / entity**

Kashan University of Medical Sciences

**Full name of responsible person**

Hosein Mahmoudzadeh

**Position**

resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Pediatrics

**Street address**

Kashan - Qutb Ravandi Boulevard - Kashan University of Medical Sciences

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**Province**

Isfahan

**Postal code**

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**Phone**

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**Email**

mahmoudzadeh-h@mail.kaums.ac.ir

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Kashan University of Medical Sciences

**Full name of responsible person**

Hosein Mahmoudzadeh

**Position**

Residency

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Pediatrics

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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Kashan University of Medical Sciences  
**Full name of responsible person**  
Hosein Mahmoudzadeh  
**Position**  
resident  
**Latest degree**  
Medical doctor  
**Other areas of specialty/work**  
Pediatrics  
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**Phone**  
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**Email**  
mahmoudzadeh-h@mail.kaums.ac.ir

## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

### Study Protocol

Yes - There is a plan to make this available

### Statistical Analysis Plan

Yes - There is a plan to make this available

### Informed Consent Form

Yes - There is a plan to make this available

### Clinical Study Report

Yes - There is a plan to make this available

### Analytic Code

Yes - There is a plan to make this available

### Data Dictionary

Not applicable

### Title and more details about the data/document

Some data, such as information about the main outcome,  
can be shared

### When the data will become available and for how long

Access period 2 months after printing the results

### To whom data/document is available

Academic researchers

### Under which criteria data/document could be used

To prevent diseases and conduct similar studies

### From where data/document is obtainable

Author

### What processes are involved for a request to access data/document

By email

### Comments