Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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

Isfehan

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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Email

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

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Email

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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

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Kashan - Qutb Ravandi Boulevard - Kashan University of Medical Sciences

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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
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Kashan University of Medical Sciences
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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