Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 Jun 2026

Comparing the effectiveness of topiramate treatment with haloperidol in chronic tic disorder

Protocol summary

Study aim
treatment of chronic tic disorder
Design
A clinical trial with two parallel intervention groups, without blinding, randomized, phase 2 on 32 patients. A table of random numbers was used for randomization.
Settings and conduct
This study will be conducted in 1402 in the city of Isfahan in the population of children with chronic tic disorder. The participants will be placed in one of the two treatment groups of topiramate or haloperidol. Blinding will not be done in this study.
Participants/Inclusion and exclusion criteria
This study is conducted on children aged 6 to 12 years who have the informed consent of their parents to participate in the study and do not have any other psychiatric disorder or history of any other disease.
Intervention groups
Children in this study are treated in two groups. The first group was treated with haloperidol at a dose of 0.225 to 8 mg per day and the second group was treated with topiramate at a dose of 50 to 200 mg per day.
Main outcome variables
tic

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20230803059021N1**
Registration date: **2023-08-10, 1402/05/19**
Registration timing: **prospective**

Last update: **2023-08-10, 1402/05/19**
Update count: **0**
Registration date
2023-08-10, 1402/05/19

Registrant information
Name
Fahime Rezaie
Name of organization / entity
Country
Iran (Islamic Republic of)
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+98 913 328 9507
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rezaeedr022@gmail.com

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2023-08-23, 1402/06/01
Expected recruitment end date
2023-09-23, 1402/07/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparing the effectiveness of topiramate treatment with haloperidol in chronic tic disorder

Public title
topiramate treatment with haloperidol in chronic tic disorder
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
parental informed consent DSM-V criteria for chronic tic disorder age between 6 and 12
Exclusion criteria:
Presence of major medical disorders such as epilepsy, diabetes, heart and kidney diseases mental retardation

Hypersensitivity to topiramate and haloperidol The presence of concomitant psychiatric disorders that require drug intervention History of long QT syndrome, cardiac arrhythmia, kidney stones and concurrent use of carbonic anhydrase inhibitor drugs

Age
From **6 years** old to **12 years** old

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **32**

Randomization (investigator's opinion)
Randomized

Randomization description
First, with the help of a random number table, a number of random numbers were generated according to the sample size, and then they were placed in sealed envelopes in this order and numbered on the envelopes. Then, according to the order in which the participants entered the study, an envelope is opened and a random sequence is determined.

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 of Isfahan University of Medical Sciences

Street address
Hezar Jarib

City
Isfahan

Province
Isfehan

Postal code
8974673461

Approval date
2023-04-29, 1402/02/09

Ethics committee reference number
IR.MUI.MED.REC.1402.059

Health conditions studied

1

Description of health condition studied
chronic tic disorder

ICD-10 code
F95.1

ICD-10 code description
Chronic motor or vocal tic disorder

Primary outcomes

1

Description
tic

Timepoint
before treatment and 1 month after and 2 month after

Method of measurement
Yale Global Tic Severity scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Treatment with haloperidol manufactured by Subhan Daru company in the form of 0.25 to 8 mg daily for 2 months

Category
Treatment - Drugs

2

Description
Intervention group: Treatment with topiramate drug manufactured by Elixir Danesh company in the form of 50 to 200 mg daily for 2 months

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Amin hospital

Full name of responsible person
Fahime Rezaie

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

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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

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Faime Rezaie

Position

Resident

Latest degree

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
no more information
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available