Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of the effects of Topiramate and Gabapentin in Opioid withdrawal syndrome

Protocol summary

Study aim

Comparison of the effect of gabapentin with topiramate on the effects of opioid withdrawal syndrome with the aim of finding a more effective drug in this field to prevent relapse

Design

A randomized, non blinded, Controlled clinical trial with parallel groups

Settings and conduct

This study is a controlled clinical trial performed on 60 patients admitted to the psychiatric ward of Shariati Hospital of Fasa who are opioid dependent according to the criteria of the Diagnostic and Statistical Manual of Mental Disorders and are admitted to this hospital for detoxification. The instrument for measuring the severity of withdrawal symptoms is the questionnaire of Subjective opiate withdrawal scale, which includes 16 opioid withdrawal symptoms and each symptom is scored from zero to 4 based on severity. In each patient, this questionnaire is completed every two days. .

Participants/Inclusion and exclusion criteria

Conditions for entering the study: Detection of opioid dependence according to DSM-V criteria Conditions for not entering the study: Major medical diseases, Pregnancy and lactation period

Intervention groups

Patients in the first group receive 300-1200 mg of gabapentin daily and patients in the second group receive 100-300 mg of topiramate daily for one to a maximum of three weeks.

Main outcome variables

The main outcome variable includes the score of opioid withdrawal syndrome, which is measured in 6 stages including the first day before the intervention and the 3rd, 5th, 7th, 9th and 11th days after starting gabapentin or topiramate through a questionnaire.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210427051102N1**
Registration date: **2021-05-16, 1400/02/26**
Registration timing: **prospective**

Last update: **2021-05-16, 1400/02/26**
Update count: **0**

Registration date

2021-05-16, 1400/02/26

Registrant information

Name
Bahare Fakhraei
Name of organization / entity
Country
Iran (Islamic Republic of)
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+98 71 5331 5749
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b.fakhraee@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-06-22, 1400/04/01

Expected recruitment end date

2021-09-23, 1400/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effects of Topiramate and Gabapentin in Opioid withdrawal syndrome

Public title
Comparison of the effects of Topiramate and Gabapentin in Opioid withdrawal syndrome
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Detection of opioid dependence according to DSM-V criteria
Exclusion criteria:
Major medical diseases including cardiovascular, pulmonary, renal and gastrointestinal disorders
Pregnancy and Lactation period
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
We put 60 cards in the envelope, 30 of which are written with gabapentin and the other 30 with topiramate and we ask the patient to choose one of the cards, and the selected card shows which group the patient belongs to.
.
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 Fasa University of Medical Sciences
Street address
Ibn Sina Square, Fasa university of medical science
City
Fasa
Province
Fars
Postal code
7461686688
Approval date
2021-03-06, 1399/12/16
Ethics committee reference number
IR.FUMS.REC.1399.175

Health conditions studied

1

Description of health condition studied
Opioid Withdrawal syndrome
ICD-10 code
F11.23
ICD-10 code description
Opioid dependence with withdrawal

Primary outcomes

1

Description
The score of Opioid Withdrawal Syndrome in the Questionnaire
Timepoint
Before intervention and 3, 5, 7, 9 and 11 days after starting gabapentin or topiramate
Method of measurement
Subjective Opiate Withdrawal Scale

Secondary outcomes

empty

Intervention groups

1

Description
Patients in the first group take 300-1200mg of oral Gabapentin daily from Poursina company for one to a maximum of three weeks.
Category
Treatment - Drugs

2

Description
Patients in the second group take 100-300 mg of topiramate daily from Sobhan Daru Company for one to a maximum of three weeks.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shariati hospital
Full name of responsible person

Dr.Bahare Fakhraei
Street address
Shahid Dr. Fayyaz Bakhsh St.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Fasa University of Medical Sciences
Full name of responsible person
Dr.Mojtaba Farjam
Street address
Ibn Sina Square, Fasa University of Medical Sciences and Health Services, Additional Building, Ground Floor, Office of the Vice Chancellor for Research and Technology
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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
Fasa 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
Fasa University of Medical Sciences
Full name of responsible person
Parmida Rajabi
Position
Medical student
Latest degree
Medical doctor
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Person responsible for updating data

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Medical student
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Medical doctor
Other areas of specialty/work

General Practitioner

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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

Yes - There is a plan to make this available

Title and more details about the data/document

All personal data of study participants can be shared after identifying individuals.

When the data will become available and for how long

The beginning of the access period from 1401

To whom data/document is available

researchers and people working in medical universities of the country

Under which criteria data/document could be used

For research purposes and in collaboration with Fasa University of Medical Sciences

From where data/document is obtainable

Dr. Mojtaba Farjam Faculty Member of Fasa University of Medical Sciences

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

Contact with Dr. Mojtaba Farjam, the project manager via email : farjam.md@gmail.com

Comments