Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The effect of adding topiramate (compared to placebo) in reducing withdrawal symptoms in opium-like substances in the substance-dependent patients

Protocol summary

Summary

Aims evaluation of the efficacy of topiramate in patient undergoing treatment for opiate withdrawal. Design a two-week double-blind, randomized, placebo-controlled of adjunctive topiramate in methadone-assisted detoxification(MAD). Setting Specialized Addictive Behaviors Unit (Ibn-e-Sina hospital), an in-patient unit for the treatment of patients with an addictive disorder serving the city of Mashhad (Iran). Participants forty in-patients, all males aged 20-61 years, who met DSM-IV criteria for opiate dependence. Intervention random assignment of subjects to receive adjunctive treatment with either topiramate (100 mg/day) or placebo under double-blind conditions. Measurements Severity of subjective withdrawal symptoms using the Subjective Opiate Withdrawal Scale at five stages.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201307205280N14**
Registration date: **2013-08-02, 1392/05/11**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2013-08-02, 1392/05/11

Registrant information

Name

Raheleh Nejati

Name of organization / entity

Mashhad University of Medical Scinces, Ibn-e- Sina Psychiatric Hospital

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2012-04-03, 1391/01/15

Expected recruitment end date

2013-04-04, 1392/01/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of adding topiramate (compared to placebo) in reducing withdrawal symptoms in opium-like substances in the substance-dependent patients

Public title

The effect of adding topiramate (compared to placebo) in reducing withdrawal symptoms in opium-like substances in the substance-dependent patients

Purpose

Treatment

Inclusion/Exclusion criteria

Individuals are included if they fulfil DSM-IV-TR criteria for opioid- like substance dependency. However, Patients are not included if they have opioid- like withdrawal syndrome during the recruitment period. Exclusion criteria: concomitant use of alcohol, stimulants as well as benzodiazepines; having severe medical comorbidities;

patients who start to take any psychiatric medication or any significant change in dose of medication during the study and follow-up period.

Age
From **19 years** old to **59 years** old

Gender
Male

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **42**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Shahid Beheshti University of Medical Sciences

Street address
Shahid Beheshti University of Medical Sciences, Tehran

City
Tehran

Postal code

Approval date
2012-03-10, 1390/12/20

Ethics committee reference number
1068

Health conditions studied

1

Description of health condition studied
opioid withdrawal symptoms

ICD-10 code
F11

ICD-10 code description
Mental and behavioural disorders due to use of opioids

Primary outcomes

1

Description
Severity of subjective withdrawal symptoms

Timepoint
At the days: 1, 3, 5, 7 and 14

Method of measurement
(OWSC) opiate withdrawal symptoms checklist

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: receive topiramate (100 mg/day), 2 weeks.

Category
Treatment - Drugs

2

Description
Control group: receive placebo for 2 weeks.

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Ebn-e- sina hospital

Full name of responsible person

Street address

City
Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Dr Farid Hoseini

Street address
Tehran

City
Tehran

Grant name

Grant code / Reference number

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

Title of funding source
Shahid Beheshti 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

Person responsible for general inquiries

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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