

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 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**Contact****Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

Dr Amir Rezaei Aardani

Position

Assistant professor

Other areas of specialty/work**Street address**

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Web page address**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