

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

08 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)

###### Phone

+98 51 3711 2540

###### Email address

nejatir2@mums.ac.ir

###### 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*