

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### A comparative study of Pregabalin and gabapentin on the control of opioid withdrawal symptoms

#### Protocol summary

##### Summary

We are going to compare the effects of pregabalin, gabapentine and placebo on the control of opioid dependence withdrawal symptoms. Inclusion criteria are: having DSM-V criteria for drug dependence; regular orally/smoking daily consumption of opium; using no other medication including psychiatric drugs and also other substances except cigarette; not taking pain medications; absence of other comorbid psychiatric disorders; not having any special disease which causes opium withdrawal prohibition; no contraindication for pregabalin and gabapentin consumption .Exclusion criteria are: lack of patients' interest for participation and continuation of study; any ethical or medical conflict for continuation; incidence of any physical/mental complication that needs special interventions.;pregnancy and breastfeeding. Study population includes all opium addicted persons who are referring to addiction treatment center of Khorshid Hospital in Isfahan, Sixty non-injecting opium users in the range of 20-50 years old who were diagnosed as opium dependent based on Diagnostic and Statistical Manual of Mental Disorders V (DSM-V) will be select as the study sample based on inclusion and exclusion criteria from April to august 2017 . All of them undergoing an as usual treatment with buprenorphine and randomly assigning in 3 groups of gabapentine, pregabalin and placebo as adding therapy (20 in each group). The severity of withdrawal symptoms will be evaluated in first, 7th, 15th and 22th days using SOWS by a resident of psychiatry.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201707252266N7**

Registration date: **2017-08-10, 1396/05/19**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2017-08-10, 1396/05/19

##### Registrant information

###### Name

Gholamreza Kheirabadi

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 31 1222 2135

###### Email address

kheirabadi@bsrc.mui.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Vice chancelor for research of Isfahan University of Medical Sciences

##### Expected recruitment start date

2017-04-04, 1396/01/15

##### Expected recruitment end date

2017-08-01, 1396/05/10

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

A comparative study of Pregabalin and gabapentin on the control of opioid withdrawal symptoms

##### Public title

comparisson of gabapentne and pregabalin in controlling of opioid withdrawal

##### Purpose

Treatment

## Inclusion/Exclusion criteria

Inclusion criteria: having DSM-V criteria for drug dependence; regular orally/smoking daily consumption of opium; using no other medication including psychiatric drugs and also other substances except cigarette; not taking pain medications; absence of other comorbid psychiatric disorders; not having any special disease which causes opium withdrawal prohibition; no contraindication for pregabalin and gabapentin consumption . Exclusion criteria : lack of patients' interest for participation and continuation of study; any ethical or medical conflict for continuation; incidence of any physical/mental complication that needs special interventions. ;pregnancy and breastfeeding.

## Age

From **20 years** old to **50 years** old

## Gender

Both

## Phase

N/A

## Groups that have been masked

*No information*

## Sample size

Target sample size: **60**

## 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

Isfahan University of medical sciences

##### Street address

Isfahan

##### City

Isfahan

##### Postal code

#### Approval date

2017-03-10, 1395/12/20

#### Ethics committee reference number

IR.MUI.REC.396.1396.3.117

## Health conditions studied

### 1

#### Description of health condition studied

Opium Dependency

#### ICD-10 code

F11

#### ICD-10 code description

Mental and behavioural disorders due to use of opioids

## Primary outcomes

### 1

#### Description

severity of opium withdrawal

#### Timepoint

first, 7th, 15th and 22th days

#### Method of measurement

Qustionair

## Secondary outcomes

### 1

#### Description

drugs sideeffects

#### Timepoint

first, 7th, 15th, 22th days

#### Method of measurement

check list

## Intervention groups

### 1

#### Description

pregabalin group:patients in this groups will be receive Bupronorphine. Bupronorphine dose will be adjusted based on patients need and all of them will be stabilized on Bupronorphine during 3-5 days. We will start tapering of Bupronorphine at 7th days with a same pattern for all the patients during 2 weeks and the final dose of Bupronorphine will be prescribed at 21th day. Pegabalin produced by sobhan darou Tehran,Iran will be started with dose of 150mg in the first week and the dose will be increased to 300mg for next week. Finally in 3rd and 4th weeks patients will be recieve 450mg of pregabalin/day.

#### Category

Treatment - Drugs

### 2

#### Description

Gabapentine group: patients in this groups will be receive Bupronorphine. Bupronorphine dose will be adjusted based on patients need and all of them will be stabilized on Bupronorphine during 3-5 days. We will start tapering of Bupronorphine at 7th days with a same pattern for all the patients during 2 weeks and the final dose of Bupronorphine will be prescribed at 21th day. We will start tapering of Bupronorphine at 7th days with a same pattern for all the patients during 2 weeks and the

final dose of Bupronorphine will be prescribed at 21th day. Gabapentine produced by sobhan darou Tehran, Iran will be started with dose of 400 mg/day in the first week, 800mg in second week and the dose will be increased to 1600mg in 3rd and 4th weeks

**Category**

Treatment - Drugs

**3****Description**

Placebo group: patients in this groups al so will be receive Bupronorphine. Bupronorphine dose will be adjusted based on patients need and all of them will be stabilized on Bupronorphine during 3-5 days. We will start tapering of Bupronorphine at 7th days with a same pattern for all the patients during 2 weeks and the final dose of Bupronorphine will be prescribed at 21th day. Placebo produced by department of pharmacology in Isfahan University of medical sciences will be started and continued in the same manner of gabapentine and pregabalin groups.

**Category**

Treatment - Drugs

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Outpatient Addiction treatmen centre of Khorshid Hospital

**Full name of responsible person**

Gholam Reza kheirabadi

**Street address**

Depoartment of Psychiatry, Isfahan University of Medical Sciences

**City**

Isfahan

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Isfahan University of Medical Sciences

**Full name of responsible person**

Dr Nematbakhsh

**Street address**

Vice chancelor for resaerch of Isfahan University of Medical Sciences

**City**

Isfahan

**Grant name****Grant code / Reference number**

396117

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

Yes

**Title of funding source**

Isfahan 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**

Isfahan University of Medical Sciences

**Full name of responsible person**

Dr Gholam Reza Kheirabadi

**Position**

Psychiatrist

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

Department of psychiatry, Isfahan University of Medical Sciences

**City**

Isfahan

**Postal code****Phone**

+98 31 3222 2135

**Fax****Email**

kheirabadi@bsrc.mui.ac.ir

**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Isfahan University of Medical Sciences

**Full name of responsible person**

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**Web page address**

## Person responsible for updating data

### Contact

**Name of organization / entity**

Isfahan University of Medical Sciences

**Full name of responsible person**

Dr Gholam Reza Kheirabadi

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

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Medical Sciences

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Isfahan

**Postal code****Phone**

+98 31 3222 2135

**Fax****Email**

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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*