Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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 pregabaline, 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 buprenorhpine 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
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Iran (Islamic Republic of)
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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 controling 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 brestfeeding.
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 sideffects
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 Psychiatryy, 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

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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