Clinical Trial Protocol
Iranian Registry of Clinical Trials

21 Nov 2026

Assessment of adding Pregabalin to daily treatment regimen in reducing withdrawal symptoms in opioid dependent patients

Protocol summary

Summary

The aim of current study is to assess the effects of pregabalin on opiate withdrawal syndrome in a clinical-trial. This study will be conducted on thirty patients, including 28 males and 2 females. Main inclusion criterion is being drug-dependent based on DSM-V criteria. Patients will be divided into two groups through decussate method based on visiting time. Intervention group will receive pregabalin and control one will be treated with placebo. Pregabalin will be started at the dose of 150mg/day in the first week and the dose will be increased to 300mg/day for second week. Finally in 3rd and 4th weeks, patients will administer 450mg/day and since then, pregabalin will be tapered. Placebo is produced in the same shape as pregabalin, by Pharmacy Faculty, Isfahan University of Medical Sciences. Patients in both groups are under bupronorphine treatment at first. Bupronorphine dose will be adjusted based on patients need and also will be tapered during first week of study. Patients' evaluation is based on Short Opioid Withdrawal Scale (SHOWS) including 10 questions on physical and mental symptoms/signs. They are scored from 0 (no symptoms/signs) to 3 (symptoms/signs). The assessment will be performed through interview by a psychiatry resident. Evaluation will be started before intervention and will be proceeded for 4 weeks of pregabalin use. Adverse effects of pregabalin will be assessed as well.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201702012266N6**
Registration date: **2017-04-11, 1396/01/22**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2017-04-11, 1396/01/22

Registrant information

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Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Isfahan University of Medical Sciences

Expected recruitment start date

2015-01-01, 1393/10/11

Expected recruitment end date

2016-03-19, 1394/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessment of adding Pregabalin to daily treatment regimen in reducing withdrawal symptoms in opioid dependent patients

Public title

Pregabalin effect on opioid withdrawal symptoms

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: being drug dependent based on DSM-V criteria; regular oral/smoking daily consumption of opium; using no other medication including psychiatric drugs and also other substances except cigarette; not using pain medications; absence of other comorbid psychiatric disorders; not having any special diseases in which addiction treatment is prohibited; no contraindication for pregabalin consumption; no use of any other medication interacting with pregabalin. Exclusion criteria: lack of patients' interest for participation in the study.

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Not 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

Ethics committee of Isfahan University of Medical Sciences

Street address

Isfahan University of Medical Sciences, Hezar Jarib St, Isfahan, Iran

City

Isfahan

Postal code

Approval date

2014-09-23, 1393/07/01

Ethics committee reference number

395274

Health conditions studied

1

Description of health condition studied

opiod withdrawal symptoms

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Opioid withdrawal symptoms including; feeling sick; stomach cramps; muscle spasms or twitching; feeling cold; heart pounding; muscular tension;aches and pains;yawning;runny/watery eyes; difficulty sleeping

Timepoint

At the begining of the intervention initiation, at the end of 1st week, at the end of 2nd week and at the end of 3rd and 4th weeks

Method of measurement

based on SHOWS questionnaire

Secondary outcomes

1

Description

Side effects including; Vertigo; Drowsiness; Fatigue; Weight Gain; Tremor; Constipation; Mouth dryness

Timepoint

end of 1st week, end of 2nd week, end of 3rd week and end of 4th week

Method of measurement

questionnaire

Intervention groups

1

Description

Intervention group: Pregabalin tab, oral administration, 150mg/day in 1st week, 300mg/day in 2nd week and 450mg/day in 3rd and 4th weeks

Category

Treatment - Drugs

2

Description

Control group: placebo tab, oral administration, one tab for 1st week, 2 tabs for 2nd week and 3 tabs for 3rd and 4th weeks

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Noor and Ali-Asghar Hospital

Full name of responsible person

Dr. Shahryar Moazeni

Street address

Psychiatric Department, Nour and Ali-Asghar Hospital, Ostandari Street, Isfahan, Iran

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Isfahan University of Medical Sciences

Full name of responsible person

Dr. Shahryar Moazeni

Street address

Vice chancellor for research, Isfahan University of Medical Sciences; Faculty of Medicine; Isfahan University of Medical Sciences; Hezar-Jarib Street; Isfahan; Iran

City

Isfahan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research, 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. Shahryar Moazeni

Position

resident of psychiatry

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