Clinical Trial Protocol
Iranian Registry of Clinical Trials

31 May 2026

Investigation of Pramipexole’s possible efficacy to diminish liability to relapse of drugs of abuse: A double-blind randomized placebo-controlled study

Protocol summary

Study aim

Can pramipexole reduce the likelihood of relapse in the patients who are suffering from substance use disorder (stimulants) and what is the best tolerable dose and duration of therapy.

Design

Patients will be randomly assigned to two groups, one receiving pramipexole and the other a fully matched placebo.To keep the study double blind for researchers, staffs, and participants, masking will be kept throughout the study and all interventions will be dispensed by an off-site pharmacist.

Settings and conduct

Pramipexole will be started at 0.18 mg twice daily and gradually gone upward at weekly intervals to reach the desired therapeutic dose and will be maintained for 12 consecutive weeks. Patients will be assessed at baseline and each week for possible physical or mental problems, any noticeable adverse reaction, any co-medication and pregnancy. Urine and blood samples are taken from patients and will be examined for checking drug abuse metabolites by rapid test (the 1st, 3rd, and 6th month of the study as well as two times randomly during the study).

Participants/Inclusion and exclusion criteria

18-68 year old patients who have administered stimulants 2 times in the past month and are unable to abstain drugs for 2 times are entered. If patients have abused more than two drugs during the last 3 weeks or are pregnant/ breastfeed are disqualified.

Intervention groups

Pramipexole receiving patients and placebo receiving patients

Main outcome variables

Self-reported number of days of drug self-administration, number of days abstained from drugs, and the longest period that no addictive substance has been used. The frequency and intensity of craving and cue-induced reinstatement, Emergence of side effects, medication adherence, relative functionality, and mood.The number of consecutive negative urine tests, addiction severity index, and the periods of being stood away from any drugs of abuse.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190315043060N1**
Registration date: **2019-05-04, 1398/02/14**
Registration timing: **prospective**

Last update: **2019-05-04, 1398/02/14**
Update count: **0**

Registration date

2019-05-04, 1398/02/14

Registrant information

Name

Shokouh Arjmand

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-05-22, 1398/03/01

Expected recruitment end date

2019-12-22, 1398/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation of Pramipexole’s possible efficacy to diminish liability to relapse of drugs of abuse: A double-blind randomized placebo-controlled study

Public title

Pramipexole and relapse of stimulants abuse

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

1- Patients who have administered stimulants (i.g. methamphetamine) at least 2 days in the past month. 2- Patients who have negative urine analysis for other addictive substances or the history of co-administration of drugs of abuse for no less than 3 weeks ago 3- Patients who meet the criteria of DSM-V for substance use disorder. 4- Patients who have failed to reduce or abstain currently abused substance at least for 2 times. 5- Patients who are seeking treatment and willing to abstain. 6- Age between 18 to 65 years 7- Patients who provide written informed consent. 8- Patients who have interest and are able to take part in a 4-month treatment phase and a 3-month follow up phase study (overall of 7 months). 9- Patients are only allowed to use pain killers, drugs used for neuropathic pain (gabapentin or pregabaline), and sleep aids (only benzodiazepines and Z-drugs)

Exclusion criteria:

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

0

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization of individual patients by a calculator-generated random number sequence (CASIO ClassPad 330) is used. Patients who receive 0 in randomization are assigned in the control group and those who receive 1 are allocated in the treatment group.

Blinding (investigator's opinion)

Double blinded

Blinding description

All interventions (pramipexole and its matched placebo) will be dispensed by an off-site pharmacist in fully-similar tablets identical in shape, color, and size sufficient for a 16 week-period. The allocation assignment for each treatment pack that has been sequentially numbered can only be accessible to the pharmacist.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Kerman University of Medical Sciences

Street address

Somaye interjunction, Ibn Sina street, Jahad BLVD

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Province

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Postal code

7619813159

Approval date

2019-03-12, 1397/12/21

Ethics committee reference number

IR.KMU.REC.1397.508

Health conditions studied

1

Description of health condition studied

Addiction

ICD-10 code

F19

ICD-10 code description

Other psychoactive substance related disorders

Primary outcomes

1

Description

Pramipexole's possible effects in reducing relapse of stimulants

Timepoint

1st, 3rd, 6th month of the study and 2 periods of random sampling

Method of measurement

Questionnaires, Urine samples, Self report

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Pramipexole is started at 0.18 mg twice daily and is gradually titrated upward at weekly intervals to reach the desired therapeutic dose (i.e. the dose which is tolerable and cover the initial symptoms of withdrawal) and are maintained for 12 consecutive weeks. Dosing intervals are set the same for each intervention to maintain the study blind. Pramipexole is purchased from Osve Pharmaceuticals Co.

Category
Treatment - Drugs

2

Description
Control group: Placebo receiving groups are administered a fully matched placebo (size, color, and shape) twice daily at start for a 12-week period, that might be increased in a similar way to the treatment receiving group. Placebo is provided by Osve Pharmaceuticals.

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Shahid Beheshti Hospital and Addiction Treatment Centers

Full name of responsible person
Zohre Zand Kargar

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Jomhouri BLVD, Shahid Beheshti Hospital, Kerman, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
Vice-chancellor for research and technology

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http://kmu.ac.ir/fa/vcrt

Grant name

Grant code / Reference number

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

Title of funding source
Kerman University of Medical Sciences

Proportion provided by this source
41

Public or private sector
Public

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Academic

2

Sponsor

Name of organization / entity
Kerman University of Medical Sciences

Full name of responsible person
Kerman Neuroscience Research Center

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Grant name

Grant code / Reference number

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

Title of funding source
Kerman University of Medical Sciences

Proportion provided by this source
59

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Shokouh Arjmand

Position

Research assistant

Latest degree

Medical doctor

Other areas of specialty/work

Medical Pharmacy

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

The main outcomes and the final conclusion will be announced.

When the data will become available and for how long

When peer-review was completed and results were published.

To whom data/document is available

With permission of the research head, data can be هد شززثسس for those who ask for

Under which criteria data/document could be used

In case of a request to have access to the analyzed data, permission should be first sought, and the research team will decide on what further analyses are allowed, afterwards .

From where data/document is obtainable

Dr. Abdolreza Sabahi (abdsaba@kmu.ac.ir) Dr. Nouzar Nakhaee (nakhaeen@yahoo.com) Dr. Shokouh Arjmand (s.arjmand@kmu.ac.ir)

What processes are involved for a request to access data/document

In case of research team agreement, either raw and analyzed data are available within 2 months after the request is submitted.

Comments