

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Investigating the effects of berberis vulgaris L. on the treatment of opiate withdrawal syndrome

Protocol summary

Study aim

Evaluation of the effects of berberis vulgaris L. on the treatment of opiate withdrawal syndrome

Design

Half of the patients are randomly selected as the control group and the other half are selected as the target group. Both groups are treated with methadone and the daily dose of methadone is adjusted daily by the physician so that the signs and symptoms of substance abuse are eliminated and, if necessary, the dose is gradually increased (maximum 5-10 mg per day. The capsules filled with powdered dried plant root extract powder are given to patients in the case group (500 mg, twice a day) and capsules containing the ineffective starch (placebo).) Control group patients are prescribed. Questionnaires assessing depression, anxiety, sleep quality, and withdrawal symptoms are completed on days 0, 3, 7, 14, and 28 by the researcher.

Settings and conduct

This study was performed to investigate the effect of barberry extract on the symptoms of opioid recovery and psychological symptoms. Patients are randomly selected and the patient and physician are unaware of the content of the capsules received.

Participants/Inclusion and exclusion criteria

Inclusion criteria: opioid addiction; age between 20-60 years old with no history of medical comorbidities and history of allergy to this plant. Exclusion criteria: non-continuation of treatment; sensitivity to plant extracts and continued use of opiates during treatment.

Intervention groups

The control group that will receive the placebo and the intervention group that will receive the plant extract.

Main outcome variables

Withdrawal symptoms; neurological problems and duration of methadone treatment

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180114038356N3**

Registration date: **2020-07-16, 1399/04/26**

Registration timing: **retrospective**

Last update: **2020-07-16, 1399/04/26**

Update count: **0**

Registration date

2020-07-16, 1399/04/26

Registrant information

Name

Somayyeh Karami-Mohajeri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 34 3132 5001

Email address

somayyehkarami@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-04-19, 1398/01/30

Expected recruitment end date

2020-04-18, 1399/01/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effects of berberis vulgaris L. on the treatment of opiate withdrawal syndrome

Public title

Investigating the effects of berberis vulgaris L. on the treatment of opiate withdrawal syndrome

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Opioid addiction of at least 2.3 grams per day continuously for at least one year, Age between 20-60 years old No history of medical comorbidities No history of allergies to this plant

Exclusion criteria:

History of medical comorbidities History of allergies to this plant Do not take the capsules Dissatisfaction with methadone dose reduction Intolerance to some of side effects of the extract, such as dry mouth

Age

From **20 years** old to **60 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant

Sample size

Target sample size: **28**

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization. The size of each block was 4 people. In this way, the first block is given the capsule with code 1 and the second block is given the capsule with code 2 and the 3rd block is given the capsule with code 1 again and so on.

Blinding (investigator's opinion)

Single blinded

Blinding description

The capsules were given to the treating physician with a code, and patients are not aware of the contents of the capsules.

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

Ebn-e-Sina St., Jihad Blvd., Kerman, Iran

City

Kerman

Province

Kerman

Postal code

7619813159

Approval date

2018-05-12, 1397/02/22

Ethics committee reference number

IR.KMU.REC.1397.205

Health conditions studied**1****Description of health condition studied**

Patients addicted to opioids treated with methadone

ICD-10 code

F11

ICD-10 code description

Mental and behavioural disorders due to use of opioids

Primary outcomes**1****Description**

Examination of opioid withdrawal symptoms and neurological complications with the questionnaires

Timepoint

Before intervention and 7, 14 and 28 days after intervention

Method of measurement

Questionnaires

Secondary outcomes**1****Description**

Assessment of depression, anxiety, sleep quality

Timepoint

Before intervention and 7, 14 and 28 days after intervention

Method of measurement

Questionnaires

Intervention groups**1****Description**

Intervention group: 28 patients under methadone therapy will be assigned to the treatment group to receive the extract (500 mg, twice a day for 30 days).

Category

Treatment - Drugs

2

Description

Control group: 28 patients under methadone therapy will be assigned to the control group to receive the placebo (500 mg, twice a day for 30 days).

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Addiction treatment clinics in Kerman

Full name of responsible person

Dr. Mahin Eslami

Street address

Shahid Beheshti Educational Center, Jomhuri Eslami Blvd.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Prof. Abbas Pardakhti

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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

10

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Persons

Person responsible for general inquiries

Contact

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Somayyeh Karami-Mohajeri

Position

Assistance prof.

Latest degree

Ph.D.

Other areas of specialty/work

Toxicology

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Person responsible for scientific inquiries

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Person responsible for updating data**Contact****Name of organization / entity**

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Part of the data, such as information about the main
consequence or the like, can be shared.

When the data will become available and for how long

after publication

To whom data/document is available

people working in academic institutions or people
working in businesses

Under which criteria data/document could be used

meta analysis

From where data/document is obtainable

Email of the main executor of the project

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

Review the request by the project executor, consult with
other colleagues, announce the result

Comments