Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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., Jahad Blvd., Kernan, 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.
City
Kerman
Province
Kerman
Postal code
8-32111006
Phone
+98 34 3211 1006
Email
h_beheshti@kmu.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kerman University of Medical Sciences
Full name of responsible person
Prof. Abbas Pardakhti
Street address
Ebn-e-Sina St., Jahad Blvd., Kernan,Iran
City
Kerman
Province
Kerman
Postal code
7619813159
Phone
+98 34 3226 3855
Email
vcr@kmu.ac.ir
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
Street address
Kerman University of Medical Sciences,Medical University Campus,Haft-Bagh Highway, Kerman, Iran
City
Kerman
Province
Kerman
Postal code
7616913555
Phone
+98 34 4142 5001
Email
somayyehkarami@gmail.com

Person responsible for scientific 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
Street address
Kerman University of Medical Sciences,Medical University Campus,Haft-Bagh Highway, Kerman, Iran
City
Kerman
Province
Kerman
Postal code
7616913555
Phone
+98 34 3132 5001

Email
somayyehkarami@gmail.com

Person responsible for updating data

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.

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Toxicology

Street address
Kerman University of Medical Sciences,Medical University Campus,Haft-Bagh Highway, Kerman, Iran

City
Kerman

Province
Kerman

Postal code
7616913555

Phone
+98 34 3132 5001

Email
Somayyehkarami@gmail.com

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