Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Jun 2026

Comparison of the effect of Sophora alopecuroides and placebo on the clinical opiate withdrawal scale in opium addicts: a clinical trial

Protocol summary

Study aim

Comparison of the effectiveness of Sophora alopecuroides and placebo in the treatment of opium withdrawal syndrome

Design

Phase 3 clinical trial having parallel placebo group, triple-blind, randomized by blocking using computer generated random numbers table and sequentially numbered containers each representing a block consisting of ten patients, single-center with 100 opium addict patients is performed.

Settings and conduct

The trial setting: Izad Mehr Setayesh addiction treatment camp. Protocol: fifty patients take three 400 mg capsules of Sophora alopecuroides seed extract and 50 patients take 3 placebo capsules once daily for 8 days. Before intervention and 8 days after intervention, the groups' scores of clinical opiate withdrawal scale and blood levels of aspartate aminotransferase, alanine aminotransferase and creatinine are compared. Blinding: letters A or B are labeled on drug or placebo containers. Other specifications on the labels are completely identical. Physician, nurse, patient, data collector and those who evaluate the outcome are unaware of the nature and meaning of the letters A or B on the labels. Only the main investigator knows the nature of the labels. Patients are not aware of the type of group they are in.

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients who according to the DSM-V criteria are dependent on opium for at least 1 year. Exclusion criteria: individuals who besides opium abuse other substances except for tobacco.

Intervention groups

Fifty patients use three 400 mg capsules of Sophora alopecuroides seed extract and 50 patients use 3 placebo capsules once orally every 24 hours for 8 days.

Main outcome variables

Primary outcome variable: score of clinical opiate withdrawal scale. Secondary outcome variables: blood levels of aspartate aminotransferase, alanine aminotransferase and creatinine.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20090804002288N15**
Registration date: **2019-05-09, 1398/02/19**
Registration timing: **registered_while_recruiting**

Last update: **2019-05-09, 1398/02/19**
Update count: **0**

Registration date

2019-05-09, 1398/02/19

Registrant information

Name

Saeed Kianbakht

Name of organization / entity

Iranian Academic Center for Education, Culture and Research Institute of Medicinal Plants

Country

Iran (Islamic Republic of)

Phone

+98 26147640109

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-04-21, 1397/02/01

Expected recruitment end date

2019-06-21, 1398/03/31

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the effect of Sophora alopecuroides and placebo on the clinical opiate withdrawal scale in opium addicts: a clinical trial

Public title
Effects of Sophora alopecuroides on the opium withdrawal symptoms
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Iranian male outpatients who according to the DSM-V criteria are dependent on opium for at least 1 year Patients aged 18 to 70 years Patients whose opium dose has been constant for at least one month before study Patients residing in addiction treatment camp Patients who have not used opium for at least 5 hours before arrival in camp
Exclusion criteria:
Individuals who besides opium abuse other substances except for tobacco Patients who have other psychiatric diseases Individuals who have other important diseases like cardiac, renal and hepatic disease Individuals who have organic brain disease Individuals who have mental retardation
Age
From **18 years** old to **70 years** old
Gender
Male

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **100**
Randomization (investigator's opinion)
Randomized
Randomization description
Block randomization using computer generated random numbers and sequentially numbered containers each representing a block of ten patients is used for treatment assignment.
Blinding (investigator's opinion)
Triple blinded
Blinding description
Blinding: letters A or B are labeled on drug or placebo containers. Other specifications on the labels are completely identical. Physician, nurse, patient, data collector and those who evaluate the outcome are unaware of the nature and meaning of the letters A or B on the labels. Only the main investigator knows the nature of the labels. Patients are aware that they are either in the drug or in the placebo group, but they are not aware of the type of group they are in.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Tehran University of Medical Sciences
Street address
Building number 1 of Tehran University of Medical Sciences Faculty of Medicine, Enghelab Avenue
City
Tehran
Province
Tehran
Postal code
1417653761
Approval date
2016-07-24, 1395/05/03
Ethics committee reference number
IR.TUMS.VCR.REC.1395.350

Health conditions studied

1

Description of health condition studied
Opium addiction
ICD-10 code
F11.23
ICD-10 code description
Opioid dependence with withdrawal

Primary outcomes

1

Description
Score of clinical opiate withdrawal scale
Timepoint
Before intervention and 3 and 8 days after intervention
Method of measurement
Clinical Opiate Withdrawal Scale

2

Description
Patient global impression regarding efficacy of treatment

Timepoint
Eight days after intervention
Method of measurement
Visual analog scale (ten centimeter ruler)

Secondary outcomes

1

Description
Blood level of aspartate aminotransferase
Timepoint
Before intervention and 8 days after intervention
Method of measurement
Spectrophotometer

2

Description
Blood level of alanine aminotransferase
Timepoint
Before intervention and 8 days after intervention
Method of measurement
Spectrophotometer

3

Description
Blood level of alkaline phosphatase
Timepoint
Before intervention and 8 days after intervention
Method of measurement
Spectrophotometer

4

Description
Blood level of total bilirubin
Timepoint
Before intervention and 8 days after intervention
Method of measurement
Spectrophotometer

5

Description
Blood level of direct bilirubin
Timepoint
Before intervention and 8 days after intervention
Method of measurement
spectrophotometer

6

Description
Blood level of indirect bilirubin
Timepoint
Before intervention and 8 days after intervention
Method of measurement
Spectrophotometer

7

Description
Prothrombin time
Timepoint
Before intervention and 8 days after intervention
Method of measurement
chronometer

8

Description
Blood level of creatinine
Timepoint
Before intervention and 8 days after intervention
Method of measurement
Spectrophotometer

9

Description
Level of blood urea nitrogen
Timepoint
Before intervention and 8 days after intervention
Method of measurement
Spectrophotometer

Intervention groups

1

Description
Intervention group: fifty patients use three 400 mg capsules of Sophora alopecuroides seed extract once orally every 24 hours for 8 days.
Category
Treatment - Drugs

2

Description
Control group: fifty patients use 3 placebo capsules once orally every 24 hours for 8 days.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Izad Mehr Setayesh addiction treatment camp
Full name of responsible person
Dr. Mohammad Mehdi Mirjalili
Street address
Valad Abad
City
Mohammad Shahr
Province
Alborz
Postal code
2701566251

Phone
+98 26 3619 1519
Email
mmmirjalili@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iranian academic center for education culture and research
Full name of responsible person
Dr. Reza Hajiaghaee
Street address
ACECR Complex, Supa Boulevard, Poleh Kordan
City
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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
Iranian academic center for education culture and research
Proportion provided by this source
100
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
Iranian academic center for education culture and research
Full name of responsible person
Dr. Saeed Kianbakht
Position
Assistant professor
Latest degree
Ph.D.
Other areas of specialty/work
Pharmacology
Street address
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Person responsible for updating data

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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

Yes - There is 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

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

All collected deidentified IPD are to be shared.

When the data will become available and for how long

Access period starting 6 months after publication for 1 year.

To whom data/document is available

Researchers working in university and scientific and industrial institutes.

Under which criteria data/document could be used

Only statistical analyses mentioned in the article resulting from the study for personal knowledge are permitted. Written request for access to data and documents and its aim must be certified by the highest ranking official of the work place of the requester.

From where data/document is obtainable

Dr. Saeed Kianbakht with the address ACECR Institute of Medicinal plants, P.O. Box: 31375-369, Iran.

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

Written request should be sent to the address Dr. Saeed Kianbakht, ACECR Institute of Medicinal Plants, P.O. Box: 31375-369, Iran. The documents or data file will be sent to the requester by email.

Comments