

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

Email address

kianbakht@imp.ac.ir

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

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Mohammad Shahr

Province

Alborz

Postal code

2701566251

Phone
+98 26 3619 1519
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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

Karaj

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3365166571

Phone

+98 26 3476 4010

Email

hajiaghaee@imp.ac.ir

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

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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