

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

31 May 2026

### Comparison of the effect of *Sophora alopecuroides* var. *alopecuroides* and placebo on the clinical opiate withdrawal scale in heroin addicts: a clinical trial

#### Protocol summary

##### Study aim

Comparison of the effectiveness of *Sophora alopecuroides* var. *alopecuroides* and placebo in the treatment of heroin withdrawal symptoms

##### 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 heroin 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 the plant's 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 heroin for at least 1 year.  
Exclusion criteria: individuals who besides heroin abuse other substances except for tobacco.

##### Intervention groups

Fifty patients use three 400 mg capsules of the plant's 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: **IRCT20090804002288N16**

Registration date: **2020-02-15, 1398/11/26**

Registration timing: **prospective**

Last update: **2020-02-15, 1398/11/26**

Update count: **0**

##### Registration date

2020-02-15, 1398/11/26

##### 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

2020-02-20, 1398/12/01

##### Expected recruitment end date

2021-02-19, 1399/12/01

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

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

**Public title**

Effects of Sophora alopecuroides var. alopecuroides on the heroin withdrawal symptoms

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Iranian male outpatients who according to the DSM-V criteria are dependent on heroin for at least 1 year  
Patients whose urinalysis result for detection of 6-acetylmorphine is positive  
Patients aged 18 to 70 years  
Patients whose heroin dose has been constant for at least one month before study  
Patients residing in addiction treatment camp  
Patients who have not used heroin for at least 5 hours before arrival in camp

**Exclusion criteria:**

Individuals who besides heroin 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
- 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**

Letters A or B are labeled on herbal 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 Iran University of Medical Sciences

**Street address**

Hemmat Highway between Chamran and Sheykh Fazlallah Iran University of Medical Sciences Central Headquarters Fifth Floor

**City**

Tehran

**Province**

Tehran

**Postal code**

1449614535

**Approval date**

2020-02-08, 1398/11/19

**Ethics committee reference number**

IR.IUMS.REC.1398.1128

**Health conditions studied**

**1**

**Description of health condition studied**

Heroin 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 the Sophora alopecuroides var. alopecuroides seed hydro-alcoholic extract once orally every 24 hours for 8 days. The extract is produced in the Institute of Medicinal Plants affiliated to the Iranian Academic Center for Education, Culture and Research. The patients do not receive any other drug or treatment.

### **Category**

Treatment - Drugs

## 2

### **Description**

Control group: fifty patients use three 400 mg placebo capsules containing maltodextrin once orally every 24 hours for 8 days. The placebo is produced in the Institute of Medicinal Plants affiliated to the Iranian Academic Center for Education, Culture and Research. The patients do not receive any other drug or treatment.

### **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**

Karaj

**Province**

Alborz

**Postal code**

2701566251

**Phone**

+98 26 3619 1519

**Email**

mmmirjalili@yahoo.com

## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**

Vice Chancellor for Research, Research Institute for Islamic and Complementary Medicine

**Full name of responsible person**

Dr. Ali Ghobadi

**Street address**

Number 9, Pirnia Alley, Lalehzar Shomali Street, Jomhoori Eslami Avenue

**City**

Tehran

**Province**

Tehran

**Postal code**

1145847111

**Phone**

+98 21 3397 2108

**Email**

ghobadi.a@iums.ac.ir

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Vice Chancellor for Research, Research Institute for Islamic and Complementary Medicine

**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**

Institute of Medicinal Plants, ACECR Complex, Supa Boulevard, Poleh Kordan

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kianbakht@imp.ac.ir

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<http://www.imp.ac.ir>

## Person responsible for scientific inquiries

**Contact**

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**Full name of responsible person**

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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**