

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jun 2026

The investigation of effect of Hab-o-Shefa in control of withdrawal symptoms in treatment of opioid addiction to acute detoxification.

Protocol summary

Summary

This study will be designed to evaluate the efficacy of administration of Hab-o Shefa during 21 days in the management of acute opioid withdrawal. A total of 90 treatment-seeking opioid dependents will be admitted and randomly assigned to three groups (placebo, Hab-o Shefa and clonidine groups) in a double blind, controlled trial, using a computer-generated list of random numbers. The study will be conducted from September of 2011 through December of 2011 on the addiction center Tavalod-e Dobare (the major addiction center affiliated with Welfare Organization, Iran). They will be evaluated prior to admission with ECG and medical history and physical examination and will be assessed after admission with Laboratory tests including CBC, FBS, TG, Chole, AST, ALT, BUN, Crea, Na, K. Common study design for 3 groups included; 1st day each patients receive one purple capsule (cap) and four pink capsules (caps), 2th day receive 2 purple caps and 4 pink caps, 3th - 7th days receive 3 purple and 4 pink caps in four divided doses, 8th - 11th days receive 3 purple and 3 pink caps, 12th - 18th days 3 purple and 2 pink caps, 19th day 2 purple and 1 pink caps, 20th day 1 purple and 1 pink caps. For placebo group all caps contains sugar, for Hab-o Shefa group pink caps; each cap contain 750 mg Hab-o Shefa and purple caps contain sugar, for clonidine group purple caps; each cap contain 0.2 mg clonidine and pink caps contain sugar. Variables that will be checked daily by the investigator and recorded in forms included retention in treatment, rates of successful detoxification, the Subjective Opiate Withdrawal Scale (SOWS) scores, the Objective Opiate Withdrawal Scale (OOWS) scores, Clinical opioid withdrawal Scale (Cows) Scores, intensity of craving, depression Bek, depression Hamilton, drug side effects. The rater, a fourth year resident of Traditional Iranian Medicine (TIM) who will be trained in the use of the scales and will be blind to treatment group. All subjects will be given informed written consent prior to admission. Subjects can

withdraw their participation at any time and transfer to a conventional detoxification treatment. The study will be conducted in accordance with the Declaration of Helsinki and was approved by the ethical committee at Shahed University and research steering committee at Shahed University of Medical Sciences.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201109107518N1**

Registration date: **2012-03-16, 1390/12/26**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2012-03-16, 1390/12/26

Registrant information

Name

Seyed mohammad Nazari

Name of organization / entity

Shahed university

Country

Iran (Islamic Republic of)

Phone

+98 21 6648 2491

Email address

smnazari@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Shahed University, Research Affairs

Expected recruitment start date

2011-09-23, 1390/07/01

Expected recruitment end date

2012-01-21, 1390/11/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The investigation of effect of Hab-o-Shefa in control of withdrawal symptoms in treatment of opioid addiction to acute detoxification.

Public title
The investigation of effect of Hab-o Shefa in control of withdrawal symptoms in opioid addicts.

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: Opioids addiction according to DSM IV; Age between 25 to 40 years old; male; Positive urinary morphine test, Exclusion criteria: Addiction to stimulants or alcohol; Acute uncontrollable physical disease; antisocial or borderline personality or inability to answer questionnaire; Not patient consent for the study; Severe withdrawal symptoms or complications and drug allergies; Beginning of the study positive urinary stimulants test or negative urinary morphine test

Age
From **25 years** old to **40 years** old

Gender
Male

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **90**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
The university shahed of Ethics committee
Street address

Shahed university, opposite of holy sanctuary imam khomani, Tehran-Qom highway, Tehran
City
Tehran
Postal code
Approval date
2011-09-11, 1390/06/20
Ethics committee reference number
118967

Health conditions studied

1

Description of health condition studied

Opioid addiction

ICD-10 code
f11.2

ICD-10 code description
Mental and behavioural disorders due to use of opioids

Primary outcomes

1

Description

Clinical withdrawal symptoms

Timepoint

Daily

Method of measurement

questionnaire according to DSM IV

2

Description

Objective withdrawal symptoms

Timepoint

Daily

Method of measurement

questionnaire according to DSM IV

3

Description

Subjective withdrawal symptoms

Timepoint

Daily

Method of measurement

questionnaire according to DSM IV

4

Description

Depression Bek

Timepoint

Daily

Method of measurement

Bek questionnaire

5

Description

Depression Hamilton
Timepoint
Daily
Method of measurement
Hamilton questionair

6

Description
craving on opioids
Timepoint
Daily
Method of measurement
Halikas questionnaire

Secondary outcomes

1

Description
Adverse effect of Hab-o-Shefa and Clonidine
Timepoint
Daily
Method of measurement
Accordingto Traditional Iranian Medicine refrences and textbook of Katzong: tachicardic arrythmia, Blurred vision, Changes in vision- photophobia, constipation, urinary disorder, vertigo, Sleep disorders, Dry mouth, nausea and vomitting, flashing

Intervention groups

1

Description
Clonidine is a specific a2-adrenergic receptor agonist that has been widely used in opioid detoxification. Treatment program in this study included the first day 0/2 mg and 2th days 0/4 mg and 3th days until 18th days 0/6mg and tapering down until 20th days and then stops.
Category
Treatment - Drugs

2

Description
Hab-o Shefa is a combination drug of Traditional Iranian Medicine that it is combination of different ratios of datura stramonium, Rheum Palmatum, Zingiber Officinalis and Acacia Arabica. This is a combined oral with daily dose of 3 g. This combination is available in capsules of 500 mg and 750 mg per capsule. Treatment program in this study included the first day four capsules daily for seven days and 3 capsules daily for eighth until eleventh days and one capsule until twentieth day and then stops.
Category
Treatment - Drugs

3

Description

In this study sugar is used as a placebo.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Medical center of Tavalod-e-Dobare
Full name of responsible person
Hasani Reza
Street address
Treatment Addiction centers of Tavalod-dobare, opposite to Metro entrances, mohamad shahr, karaj
City
Karaj

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Studies and Research affair of University shahed.
Full name of responsible person
Dr. Mohammadreza jalali
Street address
Shahed university, Opposite to holy shrine of Imam Khomainsi, Highway Tehran-Qom, Tehran
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Studies and Research affair of University shahed.
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Medicine callege of Shahed University
Full name of responsible person
seyed mohammad nazari
Position
Final year Resident of Traditional Iranian Medicine
Other areas of specialty/work

Street address

Medicine callege, Bolvare Keshavarz, Abdollah zade street,

City

Tehran

Postal code**Phone**

+98 912 808 7714

Fax**Email**

drnazari43@gmail.com

shamidrezanazari@yahoo.com

timshahed@yahoo.com

Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Traditional Iranian Medicine Groups of Shahed University

Full name of responsible person

seyed mohammad nazari

Position

final year resident of Traditional Iranian Medicine

Other areas of specialty/work**Street address**

Shahed medicine callage, Bolvar-e Keshavarz, Abdollah zade street

City

Tehran

Postal code**Phone**

+98 21 2288 2521

Fax**Email**

drnazari43@gmail.com

shamidrezanazari@yahoo.com

timshahed@yahoo.com

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

University School of Medicine of Shahed

Full name of responsible person

seyed mohammad nazari

Position

final year resident of Traditional Iranian Medicine

Other areas of specialty/work**Street address**

Medicine college, Abdollah Zadeh street, Farmer's Boulevard, Tehran

City

Tehran

Postal code**Phone****Fax****Email**

drnazari43@gmail.com

shamidrezanazari@yahoo.com

timshahed@yahoo.com

Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty