Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Sep 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 designe 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, cotroled trial, using a computer-generated list of random numbers. The study will be conducted from Ceptember 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; 1th 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)

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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; Posittive urinary morphine test, Exclusion criteria: Addiction to stimulants or alchole; Acute incontrollable to 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 senctury imam khomaini, 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

questionair according to DSM IV

2

Description

Objective withdrawal symptoms

Timepoint

Daily

Method of measurement

questionair according to DSM IV

3

Description

Subjective withdrawal symptoms

Timepoint

Daily

Method of measurement

questionair according DSM IV

4

Description

Depression Bek

Timepoint

Daily

Method of measurement

Bek questionaire

5

Description

Depression Hamilton

Timepoint

Daily

Method of measurement

Hamilton questionair

6

Description

craving on opioids

Timepoint

Daily

Method of measurement

Halikas questionaire

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 Officionalis 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 afair of University shahed.

Full name of responsible person

Dr. Mohammadreza jalali

Street address

Shahed university, Opposite to holy shrine of Imam Khomaini, 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 afair 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

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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