Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Jun 2026

effect of habb-o-shefa in maintenance treatment of opiate dependent person

Protocol summary

Summary

Purpose: assessment effect of habb-o-shefa in maintenance treatment of opiate dependent patients. Design: This study is a randomized double blind placebo controlled. Blindness done for patients and researchers. Inclusion criteria: DSM-IV criteria for addiction healthy medical condition; detoxification at least one month before intervention. Exclusion criteria: Addiction to alcohol ; positive history of other psychological disorders ; pregnancy and breast feeding; serious medical disease ; allergic reaction to medical herbs ; incidence of side effect. People in study: opiate addicted male and females 18-65 years old who referred to addiction treatment centers in Isfahan. Sample size: 60. Intervention: This study will include two groups. Each group will consist of 30 opiate addicted patients. In intervention group capsules containing 500 mg Habb-o-shefa and in control group placebo capsules containing 500 mg sugar three times a day is prescribing for 3 month (12 weeks) .Outcomes are measured by standardized questionnaires in weeks 0, 2, 4,8 and 12 after intervention in two group and will be comprised. Primary outcome: anxiety; craving; quality of life

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015101024446N1**
Registration date: **2015-11-16, 1394/08/25**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2015-11-16, 1394/08/25

Registrant information

Name

Sayyed Abdolali Moosavyzadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3792 9073

Email address

alimoosavy@yahoo.com

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research of Shahed University of Medical Sciences

Expected recruitment start date

2015-09-23, 1394/07/01

Expected recruitment end date

2016-04-20, 1395/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

effect of habb-o-shefa in maintenance treatment of opiate dependent person

Public title

effect of habb-o-shefa in treatment of adiction

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age 18 - 65 years old ; DSM-IV criteria for addiction ; healthy condition ; detoxification at least one month before intervention; signed informed consent Exclusion criteria: Addiction to alcohol ; positive history of other psychological disorders ; taking psychiatric drug ; pregnancy and breast feeding ; serious medical disease

such as glaucoma ,retention ,epilepsy ,parkinsonism ; allergic reaction to medical herbs ; incidence of side effect

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **60**

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
Ethics Committee of Shahed University

Street address
Shahed University, Opposite of Imam Khomeiny Shrine, Tehran-Qom Freeway

City
Tehran

Postal code

Approval date
2015-03-09, 1393/12/18

Ethics committee reference number
4/1233

Health conditions studied

1

Description of health condition studied
addiction

ICD-10 code
F11

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

Primary outcomes

1

Description
anxiety

Timepoint
Baseline, 4,8 and12 weeks after starting the medication

Method of measurement
Hamilton rating scale for anxiety

2

Description
craving

Timepoint
Baseline, 4,8 and12 weeks after starting the medication

Method of measurement
Craving Beliefs Questionnaire

3

Description
quality of life

Timepoint
Baseline, 4,8 and12 weeks after starting the medication

Method of measurement
wHO-QOL Brief

Secondary outcomes

1

Description
side effect

Timepoint
4,8 and12 weeks after starting the medication

Method of measurement
physical examination and checklist

Intervention groups

1

Description
Intervention group: habb-o-shefa capsule(500 mg) dose: 1 cap three time a day for 12 weeks(3 month)

Category
Treatment - Drugs

2

Description
control group: sugar capsule(500 mg) dose: 1 cap three time a day for 12 weeks(3 month)

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Treatment Addiction Centers of Etemad

Full name of responsible person
Sayyed Abdalali Moosavyzadeh

Street address
Amir Building, Ghods square, Isfahan

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Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice Chancellor for research of Shahed University of Medical Sciences

Full name of responsible person
Hasan Namdar

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Shahed university, Opposite of Imam Khomeiny shrine, Tehran-Qom freeway

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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
Vice Chancellor for research of Shahed University of Medical Sciences

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
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Full name of responsible person
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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