

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

The Effect of Hab-o-Shefa Product on craving Reduction after Detoxification Phase in Outpatients with Opioid Substance Use Disorder

Protocol summary

Study aim

Investigation on the Effect of Hab-o-Shefa Product on craving Reduction after Detoxification Phase in Outpatients with Opioid Substance Use Disorder

Design

A double blind, with parallel groups, placebo controlled clinical trial

Settings and conduct

Patients receive weekly capsules after detoxification. At the beginning and monthly until the end of the study the outcome variables are measured through questionnaires. The capsules presented to patients are also coded by a third person and the research team members are not aware of the contents of the capsules.

Participants/Inclusion and exclusion criteria

Opioid Addiction According to DSM5 criteria, no history of major physical and mental illness, equal distribution on education, occupation, and marital status between samples, no addiction to other substances except opioid substances such as stimulants

Intervention groups

Both groups will receive coded capsules for 12 weeks. The intervention group will receive three capsules 500 mg Hab-o-Shefa Product daily orally for 3 months and the control group will receive three capsules 500 mg placebo daily orally for 3 months.

Main outcome variables

craving after Detoxification Phase

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190817044547N1**

Registration date: **2019-10-01, 1398/07/09**

Registration timing: **registered_while_recruiting**

Last update: **2019-10-01, 1398/07/09**

Update count: **0**

Registration date

2019-10-01, 1398/07/09

Registrant information

Name

Mohammad Bagher Saberi zafarghandi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6655 1658

Email address

saberi.mb@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-09-22, 1398/06/31

Expected recruitment end date

2020-03-19, 1398/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Hab-o-Shefa Product on craving Reduction after Detoxification Phase in Outpatients with Opioid Substance Use Disorder

Public title

The Effect of Hab-o-Shefa Product on craving Reduction in Outpatients with Opioid Substance Use Disorder

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

All patients with opioid addiction according to the DSM V Reference Criteria who have not had other substance use disorders such as stimulants in the past year People who can answer questions and tests Blood pressure is lower than 14.9cm Hg; There is not history of major physical and mental illness There is an equal distribution on education, occupation, and marital status between samples.

Exclusion criteria:**Age**

From **15 years** old to **60 years** old

Gender

Male

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

N/A

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description

Hab-o-Shefa Product and placebo were numbered by the third person

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

No. 1471, Above Shiraz Opportunity Crossing, Kargar Shomali St., Enghelab Square

City

Tehran

Province

Tehran

Postal code

3319118651

Approval date

2018-10-29, 1397/08/07

Ethics committee reference number**Health conditions studied****1****Description of health condition studied**

Substance abuse

ICD-10 code

F11.2

ICD-10 code description

Opioid dependence

Primary outcomes**1****Description**

craving after Detoxification Phase

Timepoint

At the baseline (before intervention) and monthly until end of study

Method of measurement

Obsessive Compulsive Drug use Scale questionnaire

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: The patients will receive daily oral 500 mg of Hab-o-Shefa Product for three months.

Category

Rehabilitation

2**Description**

Control group: The patients will receive daily oral 500 mg of placebo for three months.

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Iranian Khanevade Behboodi Medical Center

Full name of responsible person

Yasha Fayaz Feyzi

Street address

Next to the Gas Station, Khoshnam Road, Azadegan Square, Meshkindasht

City

Karaj

Province

Alborz
Postal code
3155666473
Phone
+98 26 3221 9704
Email
dr_yasha_fayaz@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahed University
Full name of responsible person
Mohsen Naseri
Street address
No. 1471, Kargar Shomali Street, Enghelab Square,
Tehran, Iran
City
Tehran
Province
Tehran
Postal code
3319118651
Phone
+98 21 6646 4320
Fax
+98 21 6646 4322
Email
itmrc@shahed.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahed University

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
Iran University of Medical Sciences
Full name of responsible person
Mohammad Bagher Saberi zafarghandi
Position
Associate Professor
Latest degree
Specialist

Other areas of specialty/work

Psychiatrics

Street address

Shahied Mansuri St, Niayesh St, Sattarkhan Ave

City

Tehran

Province

Tehran

Postal code

1445613111

Phone

+98 21 6655 1658

Fax

Email

saberi.mb@iums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Yasha Fayaz Feizy

Position

M.D., Ph.D

Latest degree

Ph.D.

Other areas of specialty/work

Psychiatrics

Street address

No. 31, 5th floor, Mahdi Building, Opposite Maryam
Pharmacy, Bakhshdari Alley, Before Azadegan Bridge,
North Taleghani

City

Karaj

Province

Alborz

Postal code

3155666473

Phone

+98 26 3221 9703

Email

dr_yasha_fayaz@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Iranian Khanevade Behboodi Medical Center

Full name of responsible person

Fatemeh Ramezani

Position

Clinical Psychologist

Latest degree

Master

Other areas of specialty/work

Psychology

Street address

No. 31, 5th floor, Mahdi Building, Opposite Maryam
Pharmacy, Bakhshdari Alley, Before Azadegan Bridge,
North Taleghani

City
Karaj
Province
Alborz
Postal code
3155666473
Phone
+98 26 3221 9703
Fax
Email
faa.ramezani@gmail.com

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

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Clinical and psychological outcomes after the study

When the data will become available and for how long

1400

To whom data/document is available

Academic Researchers

Under which criteria data/document could be used

Academic Researchers

From where data/document is obtainable

web site, Email

What processes are involved for a request to access data/document

Academic Email

Comments