

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

TEffect of herbal combination of traditional medicine (Rahayesh majoon) on withdrawal symptoms, cravings, sleep quality and mental disorders of opium addicts

Protocol summary

Study aim

The aim of this study is to determine the effect of herbal combination of traditional medicine (Rahayesh majoon) on withdrawal symptoms, cravings, sleep quality and mental disorders of opium addicts.

Design

Clinical trial with control group, with parallel groups, double-blind, phase 3 randomization on 100 patients, randomization by Permuted block randomization method

Settings and conduct

This project will be conducted as a double-blind randomized clinical trial on opium addicts who refer to addiction treatment centers affiliated to Kashan University of Medical Sciences and Rafsanjan University of Medical Sciences. The first group, under the name of the intervention group, receives the full dose of methadone they need along with the herbal medicine "Rahayesh". Start this medicine with 1 to 2 teaspoons a day. After a week, the medicine is increased to 4 spoons a day. The second group, under the name of control, receives the full dose of methadone they need along with placebo. Patient information including personal characteristics, withdrawal symptoms questionnaire, drug craving questionnaire, mental disorder, sexual desire and sleep quality will be collected for patients at the beginning of the study, the second and fourth week of the study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients on methadone maintenance treatment and aged 18 to 60 years old will be included in this study. Exclusion criterion: unwillingness to cooperate.

Intervention groups

The intervention group consists of 50 participants: they receive the full dose of methadone they need along with a container of herbal medicine under the brand name "Rahayesh". The control group consists of 50

participants: they will receive the full dose of methadone they need along with placebo

Main outcome variables

Withdrawal syndrome, Craving, Sleep quality, Mental disorder, Sexual desire

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231014059714N1**

Registration date: **2023-10-26, 1402/08/04**

Registration timing: **prospective**

Last update: **2023-10-26, 1402/08/04**

Update count: **0**

Registration date

2023-10-26, 1402/08/04

Registrant information

Name

Farkhondeh Razzaghi firozjaei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 5527 2636

Email address

razzaghi-f@kaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-11-11, 1402/08/20

Expected recruitment end date

2024-01-10, 1402/10/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

TEffect of herbal combination of traditional medicine (Rahayesh majoon) on withdrawal symptoms, cravings, sleep quality and mental disorders of opium addicts

Public title

Effect of herbal combination of traditional medicine (Rahayesh majoon) in in opium addicts

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

1- Patients with addiction (diagnosis based on DSM-IV criteria) who are treated with methadone Age 65-18 years The patient has not yet reduced the dose The patient should not take a high dose of methadone. The patient should only receive methadone treatment The patient's methadone treatment time is more than 6 months, that is, it has reached a point where it is no longer necessary to increase the dose for the patient (the patient is on a stable dose of methadone) The patient should receive a dose of methadone below 50 cc daily

Exclusion criteria:

1. Every 7 days, the urine test for morphine, methamphetamine, hashish is checked, and if the test is positive, the patient is excluded from the study. The presence of certain diseases including hypothyroidism or hyperthyroidism and... High blood pressure (systolic pressure above 160 and diastolic pressure above 100 mmHg) Taking psychiatric and nerve drugs while studying, such as benzodiazepines, antidepressants, etc. Having psychotic symptoms6. Pregnant women Pregnant women Warfarin users People who are allergic to reading and report side effects caused by taking medicine while studying Use of anti-oxidant and anti-inflammatory drugs and supplements in the last 3 months and during the study.

Age

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

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization is done by block method (Permuted block randomization) so that first all 4 blocks containing two codes A and B are prepared (6 blocks) then random blocks are selected by placement using a table of random numbers. These blocks form a sample-sized sequence of A and B codes, each of which is randomly assigned to one of the groups. The list of relevant codes will remain in the formulation department of Barij Essan Company until the completion of the project and will be provided with this randomization method.

Blinding (investigator's opinion)

Double blinded

Blinding description

This study is double-blind, in order to blind the participants and patients, the drug and placebo are placed in separate packages with codes 1 and 2.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Kashan University of Medical Sciences

Street address

Kashan University of Medical Sciences, Qutb Rawandi Blvd

City

Kashan

Province

Isfahan

Postal code

8715981151

Approval date

2023-10-01, 1402/07/09

Ethics committee reference number

IR.KAUMS.MEDNT.REC.1402.152

Health conditions studied**1****Description of health condition studied**

Addiction

ICD-10 code

F19

ICD-10 code description

Other psychoactive substance related disorders

Primary outcomes

1

Description

Withdrawal syndrome

Timepoint

At the beginning of the study, the second and fourth week of the study

Method of measurement

Clinical opiate withdrawal symptoms (COWS)

2

Description

Craving

Timepoint

At the beginning of the study, the second and fourth week of the study

Method of measurement

Desire for Drug Questionnaire (DDQ craving)

Secondary outcomes

1

Description

sleep quality

Timepoint

The beginning of the study, the second and fourth week of the study

Method of measurement

Pittsburgh Sleep Quality Index (PSQI)

2

Description

anxiety

Timepoint

The beginning of the study, the second and fourth week of the study

Method of measurement

Beck Anxiety Inventory (BAI)

3

Description

Depression

Timepoint

The beginning of the study, the second and fourth week of the study

Method of measurement

Beck Depression Inventory (BDI)

4

Description

sexual desire

Timepoint

The beginning of the study, the second and fourth week of the study

Method of measurement

(IIEF)International index of erectile function

questionnaire

Intervention groups

1

Description

Taking the full dose of methadone needed along with 1 to 2 teaspoons of herbal medicine Rahayesh(Barij essence, Kashan, Iran) per day for 4 weeks.

Category

Treatment - Drugs

2

Description

Control group: Receiving the full dose of methadone along with placebo for 4 weeks

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Substance Abuse Center

Full name of responsible person

Amir Ghaderi

Street address

Mehrpavar clinic, Mehrgan Alley, 200 meters above the fire department, Mehr housing, kashan

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Province

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8718317657

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2

Recruitment center

Name of recruitment center

Clinic of Rafsanjan University of Medical Sciences

Full name of responsible person

Ali Shamsi Zadeh

Street address

Rafsanjan University of Medical Sciences, Faculty of Medicine

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Rafsanjan

Province

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7719617996

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Email
Ashamsi@rums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Kashan University of Medical Sciences

Full name of responsible person
Dr Gholamali Hamidi

Street address
Kashan University of Medical Sciences, Vice President
of Research and Technology

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hamiidi@yahoo.com

Grant name

Grant code / Reference number

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

Title of funding source
Kashan University of Medical Sciences

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
Kashan University of Medical Sciences

Full name of responsible person
Hossein Akbary

Position
Associate Professor

Latest degree
Ph.D.

Other areas of specialty/work
Biostatistics

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Associate Professor

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Person responsible for updating data

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PhD Student

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Master

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Toxicology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available