Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jul 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
Isfehan
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
Mehrparvar clinic, Mehrgan Alley,200 meters above the fire department, Mehr housing, kashan
City
Kashan
Province
Isfehan
Postal code
8718317657
Phone
+98 31 5534 9472
Email
gaderiam@yahoo.com

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
City
Rafsanjan
Province
Kerman
Postal code
7719617996
Phone
+98 34 3131 5084

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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8715981151
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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.
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Biostatistics
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Person responsible for scientific inquiries

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Full name of responsible person
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Position
Associate Professor
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Person responsible for updating data

Contact
Name of organization / entity
Kashan University of Medical Sciences
Full name of responsible person
Farkhondeh Rzazzaghi Firozjaei
Position
PhD Student
Latest degree
Master
Other areas of specialty/work
Toxicology
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Phone

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Email

farkhondehrazzaghi@yahoo.com

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