Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Effect of saffron (Crocus sativus L.) extract on oxidative stress, sex hormones and sexual dysfunction in opioid-dependent men undergoing methadone, opium tincture maintenance treatment and voluntary abstinence

Protocol summary

Study aim
Investigating the effect of saffron extract on oxidative stress, sexual dysfunction, measurement of sex hormones, prolactin and sperm parameters in the group of opioid-dependent men undergoing maintenance treatment with methadone, opium tincture and voluntary withdrawal

Design
A parallel clinical trial with a randomized control group. SPSS 26 software

Settings and conduct
De-addiction clinic centers in Semnan (Saba and Hayat) and People staying in Mehdi Shahr drug addiction camp

Participants/Inclusion and exclusion criteria
Entry:Consciously married men, without coercion, with literacy.Use of opioid substances for at least 5 years and receiving methadone and opium tincture for at least 1 year. sexual disorders with the minimum score of sexual problems Non-entry: severe anxiety disorders, depression, suicidal thoughts and withdrawal, autism, mental retardation, psychosis, bipolar and cardiovascular diseases, kidney, liver, thyroid, diabetes, digestive diseases, blood pressure, cancer diseases, AIDS

Intervention groups
group, in addition to receiving methadone maintenance treatment, tincture, and the group staying in the camp, took oral tablets of saffron extract 50 mg/day every morning for 12 weeks, and the second group, in addition to receiving methadone maintenance treatment, tincture, and staying in the camp, placebo tablets (control group)) consume Before the intervention of saffron tablets and 1 day after taking the last received dose, filling out questionnaires, taking sperm samples and taking blood from patients to determine the evaluation of parameters. After the statistical analysis of the data in the groups, a follow-up (sexual function questionnaire) is completed by the patient after 1 month

Main outcome variables
Improve sexual performance Improving the quality of sexual life Reducing relapse and craving for drug use

General information

Reason for update

Acronym
عصاره زعفران- ختلال عملکرد جنسی-متادون، تنتور اوپیوم - ترک اختیاری

IRCT registration information
IRCT registration number: **IRCT20240311061254N1**
Registration date: **2024-04-14, 1403/01/26**
Registration timing: **prospective**

Last update: **2024-04-14, 1403/01/26**
Update count: **0**

Registration date
2024-04-14, 1403/01/26

Registrant information

Name
Mehrana Mehranpour

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date

2024-06-21, 1403/04/01

Expected recruitment end date

2024-09-22, 1403/07/01

Actual recruitment start date

2024-06-21, 1403/04/01

Actual recruitment end date

2024-09-22, 1403/07/01

Trial completion date

2024-10-22, 1403/08/01

Scientific title

Effect of saffron (Crocus sativus L.) extract on oxidative stress, sex hormones and sexual dysfunction in opioid-dependent men undergoing methadone, opium tincture maintenance treatment and voluntary abstinence

Public title

Investigating the effect of saffron extract on sex hormones and sexual dysfunction in opioid-dependent men undergoing maintenance treatment with methadone, opium tincture and voluntary withdrawal

Purpose

Basic scienece

Inclusion/Exclusion criteria

Inclusion criteria:

The entry of married men knowingly, without coercion and freely, who are literate and literate, will participate in this study by filling and signing a written consent form, and they are psychologically and cognitively healthy, aware and alert. Active use of opioid substances for at least 5 years before the study and people receiving methadone or opium tincture have been under maintenance treatment with methadone or opium tincture for at least 1 year. According to the sexual disorders questionnaire, have sexual problems with a minimum score (average). Patients' evaluation: all the relevant information will be available in accordance with the ethical principles in maintaining and trusting the identity of the patients. 1- Personal characteristics: name, surname, father's name, ID number, place of birth, date of birth 2- Basic demographic characteristics: gender, marital status, level of education, occupation, weight, height, level of physical activity, race (native or not) 3- The type of narcotic used by the patients 4- Determining the dosage and duration of the narcotic in the past months 5- Examining the previous treatment history of the patients in the field of addiction, including outpatient methods, hospitalization, self-medication, staying in camps and camps etc. 6- History of sexual problems, including late or early ejaculation, dysfunction of erectile function, decreased sexual desire, sexual behavior problems, general dissatisfaction with sexual relations 7- History of prison 8- History of physical and special diseases

Exclusion criteria:

All patients who have severe anxiety, depression, stress, mental disorders (suicidal thoughts and withdrawal, dementia, autism, mental retardation, psychosis, bipolar disease, etc.) and have cardiovascular, kidney, liver, lung, thyroid, diabetes, Gastrointestinal diseases, blood pressure, all types of cancer and infectious diseases and AIDS, and they also have drug sensitivity, plant allergies, autoimmune diseases, sexual problems and congenital reproductive system, and taking medicine is harmful for them. They have absolute prohibition conditions.

Age

From **25 years** old to **50 years** old

Gender

Male

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **240**

More than 1 sample in each individual

Number of samples in each individual: **40**

There are 30 people in each group (180 people in total). With an estimate of 25% attrition, we first include 40 people in each group who are eligible to enter the study.

Actual sample size reached: **180**

More than 1 sample in each individual

Actual sample size in each individual: **30**

We include 30 people in each group.

Randomization (investigator's opinion)

Randomized

Randomization description

There are 30 people in each group (180 people in total). With an estimate of 25% attrition, we first include 40 people in each group who are eligible to enter the study. Because the work will be done in several stages, we will use the information of the initial stages to estimate the exact sample size and continue the study until reaching that number of samples, and they will be divided into two groups using blocks of four.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Investigating the sexual dysfunction of opioid-dependent patients that saffron extract can improve sexual function and improve the quality of their sexual life.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

IR.SEMUMS.REC

Street address

Five kilometers from Damghan road - Semnan University of Medical Sciences

City

Semnan

Province

Semnan

Postal code
3513138111
Approval date
2024-03-12, 1402/12/22
Ethics committee reference number
1402.302

Health conditions studied

1

Description of health condition studied
Opioid dependent men undergoing maintenance treatment with methadone, opium tincture and voluntary withdrawal
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Investigation of saffron extract on sexual dysfunction in opioid-dependent men undergoing maintenance treatment with methadone, opium tincture and voluntary withdrawal
Timepoint
Before the intervention of saffron tablets and 1 day after taking the last dose, questionnaires will be filled, sperm sampling and blood sampling will be done to determine the evaluation of the desired parameters. After the statistical analysis of the data in the relevant groups, if the saffron extract is effective after 1 month to ensure the durability of the effect of saffron on sexual function, the sexual disorders questionnaire will be completed by the patients in the form of follow-up and support.
Method of measurement
Investigation of sexual disorders based on questionnaire

Secondary outcomes

1

Description
Investigating saffron extract on oxidative stress, sex hormones, sperm parameters and craving intensity in opioid dependent men undergoing maintenance treatment with methadone, opium tincture and voluntary withdrawal
Timepoint
Before the intervention of saffron tablets and 1 day after taking the last dose, questionnaires, sperm sampling and blood sampling of patients will be done to determine the evaluation of the desired parameters. After the statistical analysis of the data in the relevant groups, if the saffron extract is effective after 1 month to ensure the durability of the effect of saffron on sexual function, the sexual disorders questionnaire will be completed by the patients in the form of follow-up and support.
Method of measurement
Investigating oxidative stress, sex hormones through blood sampling and sperm samples through marital relationships and severity of addiction and craving based on questionnaires

Intervention groups

1

Description
Intervention group: Intervention group: under maintenance treatment with methadone and opium ventor and voluntary withdrawal who are taking saffron extract tablets.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Saba and Hayat Clinic
Full name of responsible person
Asadi
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Five kilometers from Damghan road - Semnan University of Medical Sciences
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Sponsors / Funding sources

1

Sponsor
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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
Mashhad University of Medical Sciences
Proportion provided by this source
50
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
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
There is no further information
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