Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 Jun 2026

Evaluation of the effectiveness of herbal product on sexual dysfunction and testosterone levels of men undergoing methadone maintenance treatment (MMT)

Protocol summary

Study aim
Evaluation of the effectiveness of herbal product on sexual dysfunction and testosterone levels of men undergoing methadone maintenance treatment (MMT)

Design
Clinical trial with a control group, with parallel groups, double-blind, randomized, phase 2 on 60 patients. The rand function of Excel software was used for randomization.

Settings and conduct
The herbal composition will be prepared as a syrup of onion extract and honey (along with ginger). Patients will be herbal product/placebo twice a day (every 12 hours). The time required to administer the drug is about two months. Patients will be visited by a doctor and given medicine every 30 days. All patients will be tested for testosterone levels and the IIEF questionnaire will be completed at the beginning and end of the two months.

Participants/Inclusion and exclusion criteria
Men between 20 and 50 yeas who are recovering treatment from drug addiction with sexual dysfunction, without a history of treatment for this disorder for at least three months before the study and who are at the beginning of maintenance treatment with methadone and whose sexual dysfunction is not caused by other disorders (other than addiction) , not using other drugs, not addicted to alcohol, and also patients who do not have severe liver and kidney problems.

Intervention groups
Two groups of 30 men with sexual dysfunction treated with methadone randomly assinged in 1) experimental group: treatment with herbal product combination twice per day; 2) placebo group (control): administration of placebo syrup.

Main outcome variables
1. Erectile Function (EF) 2. Sexual Desire (SD) 3. Orgasmic Function (OF) 4. Intercourse Satisfaction (IS) 5. Overall Satisfaction (OS) 6. Serum testosterone level

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20230805059047N1**
Registration date: **2023-08-23, 1402/06/01**
Registration timing: **registered_while_recruiting**

Last update: **2023-08-23, 1402/06/01**
Update count: **0**

Registration date
2023-08-23, 1402/06/01

Registrant information
Name
Kamyab Alizadeh
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 21 6650 7392
Email address
kamyab_alizadeh@yahoo.com

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2023-08-23, 1402/06/01
Expected recruitment end date
2024-04-19, 1403/01/31
Actual recruitment start date
empty
Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of the effectiveness of herbal product on sexual dysfunction and testosterone levels of men undergoing methadone maintenance treatment (MMT)

Public title
Evaluation of the effectiveness of herbal product on sexual dysfunction and testosterone levels of men undergoing methadone maintenance treatment

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Men (who are recovering from drug addiction) with sexual dysfunction confirmed by a specialist Age between 20 and 50 years Not receiving special treatment for sexual dysfunction at least three months before enrolment Being at the beginning of drug addiction treatment by MMT

Exclusion criteria:
Sexual dysfunction caused by other problems (than addiction) Using other drugs (started before or during the study) Alcohol addiction Severe liver and kidney problems

Age
From **20 years** old to **50 years** old

Gender
Male

Phase
2-3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Random assignment to intervention and control groups First, using the Random number generation plugin in excel software, a table of random numbers from 1 to 60 is prepared in a non-sequential and scattered manner, and the numbers are assigned to two intervention and control groups of 30 cases. The randomization process is performed by the methodology consultant and clinical researchers are not aware of the randomization process and will only be provided with random codes from 1 to 60.

Blinding (investigator's opinion)
Double blinded

Blinding description
The patient receives the drug (intervention or placebo) in sealed envelopes that are coded. Coding is done by one of the colleagues of the project and the doctor, evaluator and patient are blinded.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethics Committees of Vice-Chancellor in Research Affairs - Shahid Beheshti University of Me

Street address
Shahid Chamran Highway - Yemen Street - Arabi Street, Shahid Beheshti University of Medical Sciences and Healthcare Services - building number two of the university headquarters - sixth floor

City
Tehran

Province
Tehran

Postal code
1985717443

Approval date
2023-07-02, 1402/04/11

Ethics committee reference number
IR.SBMU.RETECH.REC.1402.181

Health conditions studied

1

Description of health condition studied
sexual dysfunction

ICD-10 code
F11.281

ICD-10 code description
Opioid dependence with opioid-induced sexual dysfunction

Primary outcomes

1

Description
International Index of Erectile Function (IIEF) score

Timepoint
At the beginning of the study (before intervention) and 60 days after the start of taking the herbal combination

Method of measurement
International Index of Erectile Function (IIEF)

2

Description
Serum testosterone levels

Timepoint
At the beginning of the study (before intervention) and

60 days after the start of taking the herbal combination

Method of measurement

Testing blood samples to measure testosterone levels using the ELISA method

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Dava al-Basal will be prepared in the form of syrup, a combination of onion extract and honey (along with ginger). The method of making medicine (Dava al-Basal): We heat one liter of white onion juice + 50 grams of dry ginger powder + 2 kg of honey until it reaches a consistency (brix above 80). Since the daily consumption of onion in traditional medicine sources is 6.4 grams, the daily consumption of syrup based on the extract obtained from this amount of plant mass is 20 cc, which will be prescribed to the patient in two divided doses (10 cc every 12 hours). The most important components of ginger are its essential oil and resins, and control of the final products is done based on total polyphenol. The drug will be prepared in the pharmaceutical laboratory of the Faculty of Iranian Medicine, Iran University of Medical Sciences. Standardization is based on 20 to 24 mg of total polyphenol (according to gallic acid) is done in every 5 ml of syrup. "Aria Salamat Razi" company, which is approved by the Food and Drug Organization in Iran, will review the microbial tests of herbal product.

Category

Treatment - Drugs

2

Description

Control group: Placebo (Simple syrup) is based on the British Pharmacopoeia with the addition of permitted edible color B1 of Magnolia Company, which will be consumed in the same way as the intervention group.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Etminan, outpatient drug addiction treatment and rehabilitation center

Full name of responsible person

Mahboobeh-al-sadat Golchein

Street address

first floor, unit 1, No. 179, Omid doctors building, Serah Afsariyeh, 35 meteri Qasr-e-Firuzeh, second 15 meteri of Islamabad, in front of Chehl Seton Hall, Ghoroghi corner

City

Tehran

Province

Tehran

Postal code

1786863681

Phone

+98 21 3382 7033

Email

golchin.mahboubeh@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Ghorbanali Aghighi Alaghejonban

Street address

First floor, unit 1, No. 179, Omid doctors building, Serah Afsariyeh, 35 meteri Qasr-e-Firuzeh, second 15 meteri of Islamabad, in front of Chehl Seton Hall, Ghoroghi corner

City

Tehran

Province

Tehran

Postal code

1786863681

Phone

+98 21 3382 7033

Email

Aliaghighi48@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Ghorbanali Aghighi Alaghejonban

Position
PhD student of Iranian traditional medicine
Latest degree
Medical doctor
Other areas of specialty/work
Traditional Medicine
Street address
First floor, unit 1, No. 179, Omid doctors building, Serah Afsariyeh, 35 meteri Qasr-e-Firuzeh, second 15 meteri of Islamabad, in front of Chehl Seton Hall, Ghoroghi corner
City
Tehran
Province
Tehran
Postal code
1786863681
Phone
+98 21 3382 7033
Email
Aliaghighi48@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Roshanak Mokaberinejad
Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
Traditional Medicine
Street address
Department of Traditional Medicine, Faculty of Traditional Medicine, Abbaspur Street (Tavanir), not reaching Vali Asr Street, Shams Dead End
City
Tehran
Province
Tehran
Postal code
1516745811
Phone
+98 21 8877 3521
Email
rmokaberi@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Artesh University of Medical Sciences
Full name of responsible person
Kamyab Alizadeh
Position
Consultant
Latest degree
Medical doctor
Other areas of specialty/work
General Practitioner
Street address
Unit 9 No. 32 Setayedh St. Sattarkhan St.
City
Tehran
Province
Tehran
Postal code
1457665371
Phone
+98 21 3995 4956
Email
kamyab_alizadeh@yahoo.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
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
All data is potentially shareable after de-identifying individuals
When the data will become available and for how long
The access period starts 6 months after the results are published
To whom data/document is available
Researchers working in academic and scientific institutions as well as people working in the industry can apply to receive data.
Under which criteria data/document could be used
The data can be used for research purposes.
From where data/document is obtainable
Dr. Gorban Ali Aghighi should be contacted. Email: aliaghighi48@gmail.com
What processes are involved for a request to access data/document
After contact, information is sent within a few days.
Comments