Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Jul 2026

The effects of spirulina (Arthrospira platensis) supplementation compared to placebo on craving, mental health, sexual and cognitive function in opioid patients under methadone maintenance treatment

Protocol summary

Study aim
Determining the supplemental effect of spirulina on craving, mental health, sexual and cognitive function in opioid patients under methadone maintenance treatment.

Design
A randomized clinical trial with the control group, with parallel groups, double-blind, phase 3 on 50 patients, randomization by Permuted block randomization method

Settings and conduct
Place of study: addiction treatment centers affiliated with Kashan University of Medical Sciences; Study population: Opioid patients under methadone treatment; blinding: double-blind block; Blinding method: Capsules and placebos are placed in separate vials with code 1 and 2.

Participants/Inclusion and exclusion criteria
Inclusion criteria: informed consent and willingness to participate in research; positive methadone urine test; Using methadone for at least one year; being married; age range 30-50 years. Exclusion criterion: Suffering from chronic physical diseases including phenyl ketonuria, autoimmune diseases, AIDS, hepatitis, liver and kidney disorders, cardiovascular disorders, etc. at the time of entering the treatment

Intervention groups
Intervention group: patients receiving spirulina supplement; Control group: patients receiving placebo.

Main outcome variables
Mental health; sexual function

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20231101059923N2**
Registration date: **2023-12-16, 1402/09/25**
Registration timing: **prospective**

Last update: **2023-12-16, 1402/09/25**
Update count: **0**

Registration date
2023-12-16, 1402/09/25

Registrant information

Name
Freshteh Haerifar

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-12-22, 1402/10/01

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
The effects of spirulina (Arthrospira platensis) supplementation compared to placebo on craving, mental health, sexual and cognitive function in opioid patients under methadone maintenance treatment

Public title

Complementary effect of spirulina in the treatment of opioid patients under methadone maintenance treatment

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Consent and informed willingness to participate in research Positive methadone urine test Using methadone for at least one year Married men in the age range of 30-50 years

Exclusion criteria:

Suffering from chronic physical diseases including phenyl ketonuria, autoimmune diseases, AIDS, hepatitis, liver and kidney disorders, cardiovascular disorders, etc. at the time of entering the treatment

Age

From **30 years** old to **50 years** old

Gender

Male

Phase

2

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

First, the spirulina group will be coded with the letter A and the placebo group with the letter B, and then using the website www. sealedenvelope.com/simple-randomiser/v1/lists, randomization list will be prepared by selecting a sample size of 50 (two groups of 25) and permuted block randomization method (block size=4). Then, through the obtained randomization list, the subjects included in the study will be assigned to one of the two groups, A or B. For example, suppose that in the first block, the permutation order is ABBA, so the first and fourth samples will be assigned to group A and the second and third samples to group B, and the same will continue until the last sample (25th person).

Blinding (investigator's opinion)

Double blinded

Blinding description

This study is double-blind, and after selecting the samples, none of the sampled people will know about randomization and the allocation process to groups. Patients enter the study based on the randomization list. This study will try to use the placebo similar to the capsules in terms of color, size, and the number of pills for 12 weeks of intervention. The composition of the placebo in the present study is paraffin. In addition, to keeping blind the presenters and patients, pills and placebos are placed in separate vials named 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

2023-10-29, 1402/08/07

Ethics committee reference number

IR.KAUMS.MEDNT.REC.1402.186

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

Mental health

Timepoint

At the beginning of the study and the twelfth week of the study

Method of measurement

Depression, Anxiety, Stress Scale (DASS21)

2

Description

Sexual function

Timepoint

At the beginning of the study and the twelfth week of the study

Method of measurement

International Index of Erectile Function (IIEF)

Secondary outcomes

1

Description
Craving
Timepoint
At the beginning of the study and the twelfth week of the study
Method of measurement
Desire for Drug Questionnaire (DDQ craving)

2

Description
Cognitive function
Timepoint
At the beginning of the study and the twelfth week of the study
Method of measurement
Cattell–Horn–Carroll (CHC) approach

Intervention groups

1

Description
Intervention group: The patient group will be given spirulina supplement and they will consume it for 3 months, the daily dosage is two 500 mg capsules.
Category
Treatment - Drugs

2

Description
Control group: A placebo with the same appearance as spirulina capsules is prescribed for 3 months.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Substance Abuse Center, Mehrparvar Clinic
Full name of responsible person
Amir Ghaderi
Street address
Mehrparvar clinic; Mehrgan Alley; 200 meters above the fire station; Mehr Housing
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
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
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Person responsible for updating data

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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