

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

Registration timing: **prospective**

Study aim

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

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

Update count: **0**

Registration date

2023-12-16, 1402/09/25

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

Registrant information

Name

Freshteh Haerifar

Name of organization / entity

Country

Iran (Islamic Republic of)

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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

Recruitment status

Recruitment complete

Funding source

Intervention groups

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

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

Main outcome variables

Mental health; sexual function

Trial completion date

empty

General information

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

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231101059923N2**

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

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 phenylketonuria, 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

Isfahan

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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8718317657

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gaderiam@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Dr Gholamali Hamidi

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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

Fatemeh Mehrzad

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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Amir Ghaderi
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Addiction studies
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Person responsible for updating data

Contact

Name of organization / entity
Kashan University of Medical Sciences
Full name of responsible person
Freshteh Haerifar

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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