Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of eight weeks of aerobic training and NBS superfood supplement consumption on factors involved in cell death in men undergoing methadone treatment

Protocol summary

Study aim
This study was designed to investigate the combined effect of aerobic exercise, combined with the consumption of the NBS superfood dietary supplement, on cell death factors in men using methadone.

Design
Controlled clinical trial with three non-randomized intervention groups on 60 men using methadone.

Settings and conduct
Male addicts undergoing methadone treatment at Tolo Novin Omid Addiction Treatment Center in Boroujerd will be included in the study if they are eligible and will be assigned to 4 groups. This study is designed as a double-blind study, with both participants and researchers unaware of group assignment (supplement/placebo).

Participants/Inclusion and exclusion criteria
Inclusion criteria: Negative urine test for morphine, cannabis, and methamphetamine, need to use methadone maintenance treatment for at least the past three months, no autoimmune diseases, cardiovascular and pulmonary diseases, no muscle and tendon injuries; Exclusion criteria: Unwillingness to participate in the study and being sick

Intervention groups
Intervention group 1: Subjects will perform exercises three times a week for 40 minutes each time for 8 weeks and at the same time, they will receive 4.5 grams of NBS superfood supplement orally in three equal doses daily. Intervention group 2: Subjects will perform exercises three times a week for 40 minutes each time for 8 weeks and at the same time, they will receive 4.5 grams of potato starch orally in three equal doses daily. Intervention group 3: Subjects will receive 4.5 grams of NBS superfood supplement orally (soluble in water) daily in three equal doses for 8 weeks. Control group: Subjects will receive 4.5 grams of placebo (potato starch) orally (soluble in water) daily in three equal doses for 8 weeks.

Main outcome variables
Feroptosis ؛ Oxidative stress

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20141228020465N7**
Registration date: **2025-06-17, 1404/03/27**
Registration timing: **retrospective**

Last update: **2025-06-17, 1404/03/27**
Update count: **0**

Registration date
2025-06-17, 1404/03/27

Registrant information

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Fatemeh Omidali
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University of Ayatollah Boroujerdi
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-05-15, 1404/02/25

Expected recruitment end date
2025-06-15, 1404/03/25

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of eight weeks of aerobic training and NBS superfood supplement consumption on factors involved in cell death in men undergoing methadone treatment

Public title
The effect of aerobic exercise and superfood supplementation on cell death
Purpose
Basic scienece
Inclusion/Exclusion criteria
Inclusion criteria:
Negative urine test for morphine, cannabis, and methamphetamine. The need to use methadone maintenance treatment for at least the past three months, Absence of autoimmune diseases, absence of cardiovascular and pulmonary diseases absence of muscle and tendon injuries
Exclusion criteria:
Unwillingness to participate in research Being sick
Age
From **25 years** old to **35 years** old
Gender
Male

Phase
N/A
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Not randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
This study is designed as a double-blind study, so that both participants and researchers will be unaware of the group assignment (supplement/placebo). The supplement and placebo will be provided in identical packaging (in terms of appearance, labeling, and method of administration) and distributed by independent staff of the addiction treatment center who are not involved in other parts of the study.
Placebo
Used
Assignment
Factorial
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committee of the Sports Sciences Research Institute
Street address
Number 3,Fifth Alley -Mir Emad St.-Ostad Motahari St.
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Tehran
Province
Tehran
Postal code
1587958711
Approval date
2025-04-20, 1404/01/31
Ethics committee reference number
IR.SSRC.REC.1404.016

Health conditions studied

1

Description of health condition studied
Addiction
ICD-10 code
P04.4
ICD-10 code description
Newborn (suspected to be) affected by maternal use of drugs of addiction

Primary outcomes

1

Description
ferroptosis
Timepoint
Before the intervention and 8 weeks after the end of the intervention
Method of measurement
Blood sample, serum separation, ELISA kit, use of ELISA reader

2

Description
Oxidative stress
Timepoint
Before the intervention and 8 weeks after the end of the intervention
Method of measurement
Blood sample, serum separation, ELISA kit, use of ELISA reader

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: Aerobic exercise with supplement intake for 8 weeks. Exercise protocol: First, the subjects will warm up for 10 minutes at an intensity of 50% of maximum heart rate. Aerobic exercise will be performed at an intensity of 75% to 85% of maximum heart rate for 40 minutes, three times a week. Finally, the subjects will cool down for 10 minutes at an intensity of 50% of maximum heart rate. The subjects will receive the NBS Superfood supplement at a rate of 4.5 grams per day orally, dissolved in water, and daily in three equal doses: 1.5 grams in the morning, 1.5 grams in the afternoon, and 1.5 grams in the evening. The supplements will be provided by NBS Superfood (NBS Organic Company, Turkey).

Category

Lifestyle

2

Description

Intervention group 2: Aerobic exercise with placebo for 8 weeks. Subjects will first warm up for 10 minutes at an intensity of 50% HRmax. The aerobic exercise groups will perform high-intensity aerobic exercise (75% to 85% HRmax) for 40 minutes each time three times a week. Finally, subjects will cool down for 10 minutes at an intensity of 50% HRmax. The placebo will be 4.5 grams of potato starch orally per day, dissolved in water, in three equal doses: 1.5 grams in the morning, 1.5 grams in the afternoon, and 1.5 grams in the evening.

Category

Lifestyle

3

Description

Subjects will receive 4.5 grams of NBS Superfood supplement orally, dissolved in water, daily in three equal doses for eight weeks: 1.5 grams in the morning (6 am to 12 pm), 1.5 grams in the afternoon (12 pm to 6 pm) and 1.5 grams in the evening. (from 6 pm to 12 am). The supplements will be provided by NBS Superfood (NBS Organic Company, Turkey).

Category

Lifestyle

4

Description

Control group: The control group will receive only placebo for 8 weeks. They will receive 4.5 grams of potato starch orally, dissolved in water, in three equal doses: 1.5 grams in the morning, 1.5 grams in the afternoon, and 1.5 grams in the evening. They will not do any sports activities and will continue their lifestyle.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Tolo Novin Omid Center

Full name of responsible person
Masoud Rashno

Street address
Tolo Novin Omid Center,Shahid Bahonar - Health.Baharestan Crossroads.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Ayatollah Boroujerdi University

Full name of responsible person
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Grant name
Ayatollah Boroujerdi University

Grant code / Reference number

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

Title of funding source
Ayatollah Boroujerdi University

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

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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
Not applicable
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Not applicable
Analytic Code
Not applicable
Data Dictionary
Not applicable