

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The effect of 8 weeks of Royal Jelly supplementation and cache training on cardiac injury indices and oxidative stress in opium addicts quitting methadone

Protocol summary

Study aim

Determining the effect of 8 weeks of Royal Jelly supplementation and cache training on heart damage and oxidative stress indices in opium addicts quitting methadone

Design

A controlled clinical trial with a parallel-group design of 80 Subjects, Randomized by simple randomization method, Phase 2; on 80 patients

Settings and conduct

In this quasi-experimental study, referring to Naji Zahedan Addiction Treatment Center, 80 subjects are selected and divided into four groups. Blood samples are taken from patients 48 hours before the start and after the implementation of the training protocol.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Man Type of addiction: Opium Exclusion criteria: No heart disease , Not participating in sports in the last year

Intervention groups

Intervention group 1 : For eight weeks, Royal Jelly was consumed daily as an oral gel at a dose of 100 mg per kilogram of body weight. Intervention group 2 : Exercise with Cache : Subjects performed resistance exercises using Traband for 8 weeks and 3 consecutive sessions per week for 60 minutes each session. Intervention group 3 : Exercise with royal jelly supplements Subjects performed resistance exercises using Traband for 8 weeks and 3 consecutive sessions per week for 60 minutes each session. Royal jelly was also consumed daily as a oral gel at a dose of 100 mg per kilogram of body weight. Control group: No intervention, only follow up

Main outcome variables

Malondialdehyde

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170510033909N13**

Registration date: **2022-01-29, 1400/11/09**

Registration timing: **retrospective**

Last update: **2022-01-29, 1400/11/09**

Update count: **0**

Registration date

2022-01-29, 1400/11/09

Registrant information

Name

فرزانه تقیان

Name of organization / entity

دانشگاه آزاد اسلامی. واحد اصفهان

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-12-22, 1400/10/01

Expected recruitment end date

2021-12-31, 1400/10/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of 8 weeks of Royal Jelly supplementation and cache training on cardiac injury indices and oxidative stress in opium addicts quitting methadone

Public title

The effect of supplementation and exercise on indicators of heart damage and oxidative stress in individuals Addicted

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Gender Type of addiction: Opium Age range 25 to 45 years

Exclusion criteria:

No heart disease Not participating in sports in the last year

Age

From **25 years** old to **45 years** old

Gender

Male

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization method: Simple randomization;
Randomization Tool: Random Number Table;
Randomization Unit: Individual; In order to use a table of random numbers, the researcher will first determine the reading position of the table numbers. The numbers will then be considered for different groups. For example, zero to twenty-four for intervention A, twenty-five to forty-nine for intervention B, fifty to seventy-four for group C, and seventy-five to nine for group D. Then we will touch one of the numbers and move in one of the predetermined directions. The numbers will be recorded and assigned to four groups: Exercise with cache, use Royal Jelly, combination and control. In order to hide random allocation, the method of coded boxes with random sequence will be used. This method uses a number of boxes that are numbered randomly. Adequate sealing of the boxes, their apparent similarity and their weight will be ensured

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee on Research Islamic Azad University - Isfahan Branch (Khorasgan)

Street address

University Blvd, Arghavanie, East Gay Street, Isfahan

City

Isfahan

Province

Isfahan

Postal code

8155139998

Approval date

2019-02-24, 1397/12/05

Ethics committee reference number

IR.ZAUMS.REC.1397.458

Health conditions studied

1

Description of health condition studied

Addicted

ICD-10 code

F19.20

ICD-10 code description

Other psychoactive substance dependence, uncomplicated

Primary outcomes

1

Description

Malondialdehyde

Timepoint

At the beginning and end of 8 weeks of study

Method of measurement

Serum concentration of CGRP by ELISA method using the Cayman Chemical Monobind USA

Secondary outcomes

1

Description

Superoxide dismutase

Timepoint

At the beginning and end of 8 weeks of study

Method of measurement

Serum concentration of superoxide dismutase is measured by ELISA method using Ransell kit made by Randox company.

Intervention groups

1

Description

Intervention group 1 : For eight weeks, Royal Jelly was consumed daily as an oral gel at a dose of 100 mg per kilogram of body weight.

Category

N/A

2

Description

Intervention group 2 : Exercise with Cache : Subjects performed resistance exercises using Traband for 8 weeks and 3 consecutive sessions per week for 60 minutes each session. Each workout included 10 minutes of warm-up, 40 minutes of core training, and 10 minutes of cooling

Category

Rehabilitation

3

Description

Intervention group 3 : Exercise with royal jelly supplements Subjects performed resistance exercises using Traband for 8 weeks and 3 consecutive sessions per week for 60 minutes each session. Royal jelly was also consumed daily as an oral gel at a dose of 100 mg per kilogram of body weight.

Category

Rehabilitation

4

Description

Control group: No intervention, only follow up

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Zahedan Naji Addiction Treatment Center

Full name of responsible person

Mohsen Khosravi

Street address

Facing the grain office, Imam Khomeini street, Zahedan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University, Isfahan Branch (Khorasgan),
Research Deputy

Full name of responsible person

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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

Islamic Azad University, Isfahan Branch (Khorasgan),
Research Deputy

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

Islamic Azad University

Full name of responsible person

Farzaneh Taghian

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

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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