

# 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

+98 913 308 0241

##### Email address

f.taghian@khuisf.ac.ir

##### 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

##### City

Zahedan

##### Province

Sistan-va-Balouchestan

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9813913777

##### Phone

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#### Email

Baharanhospital@zaums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

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

##### Full name of responsible person

Majid Toghyani

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Khorasgan University, Arghavanie St, Isfaha

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81551-39998

##### Phone

+98 31 3500 2352

##### Email

F\_taghian@yahoo.com

#### 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

Sport Medicine

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## Person responsible for scientific inquiries

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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