

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jun 2026

The effect of saffron supplementation and endurance training on the improvement of clinical and laboratory manifestations in outpatients with coronavirus

Protocol summary

Study aim

Effectiveness of endurance training and saffron supplementation in corona patients.

Design

Clinical trial with control group, with parallel groups, double-blind, randomized, on 40 patients. The rand function of Excel software was used for randomization.

Settings and conduct

Corona patients, who refer to the health center of Koshksaray city, if they do not need hospitalization, will receive one of the interventions in a double-blind manner and in four groups of 10 people randomly.

Participants/Inclusion and exclusion criteria

This study will be conducted on patients with corona virus, and critical patients who need hospitalization will not be included in this study.

Intervention groups

Endurance training group + saffron supplementation, saffron supplementation group, endurance training group, control group that will not receive any intervention.

Main outcome variables

Clinical manifestations (cough, breathing rate, body temperature, recovery rate) laboratory (inflammatory biomarkers, C-reactive protein levels)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171129037678N1**

Registration date: **2023-08-09, 1402/05/18**

Registration timing: **retrospective**

Last update: **2023-08-09, 1402/05/18**

Update count: **0**

Registration date

2023-08-09, 1402/05/18

Registrant information

Name

Fateme Halalkhor

Name of organization / entity

University of Tabriz

Country

Iran (Islamic Republic of)

Phone

+98 41 4224 1099

Email address

fateme.halalkhor@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-01-23, 1401/11/03

Expected recruitment end date

2023-02-22, 1401/12/03

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of saffron supplementation and endurance training on the improvement of clinical and laboratory manifestations in outpatients with coronavirus

Public title

The effect of saffron and endurance exercise in patients with coronavirus

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Outpatients with covid 19

Exclusion criteria:

History of allergy to saffron and its derivatives People with liver, kidney and respiratory disorders Lactating and pregnant women

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

The patient receives the drug (intervention or comparison group) in sealed envelopes that have a code. Coding is done by one of the project colleagues and the doctor, evaluator and patient do not know anything.

Blinding (investigator's opinion)

Double blinded

Blinding description

The patient receives the drug (intervention or comparison group) in sealed envelopes that are coded. Coding is done by one of the colleagues of the project and the doctor, evaluator and patient do not know anything.

Placebo

Used

Assignment

Factorial

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Sport Sciences Research Institute

Street address

No. 3, Fifth Alley, MirEmad St., Motahari St., Tehran

City

Tehran

Province

Tehran

Postal code

1587958711

Approval date

2023-06-20, 1402/03/30

Ethics committee reference number

IR/SSRI.REC.2023.14658.2153

Health conditions studied

1

Description of health condition studied

coronavirus

ICD-10 code

B34.2

ICD-10 code description

Coronavirus infection, unspecified

Primary outcomes

1

Description

Cough

Timepoint

Before and 14 days after the start of treatment

Method of measurement

Physical examination

2

Description

breathing rate

Timepoint

Before and 14 days after the start of treatment

Method of measurement

Physical examination

3

Description

Body temperature

Timepoint

Before and 14 days after the start of treatment

Method of measurement

Physical examination

4

Description

Speed of improvement

Timepoint

Before and 14 days after the start of treatment

Method of measurement

Physical examination

5

Description

Inflammatory biomarkers

Timepoint

Before and 14 days after the start of treatment

Method of measurement

blood test

6

Description

The amount of C-reactive protein

Timepoint

Before and 14 days after the start of treatment

Method of measurement

blood test

Secondary outcomes

1

Description

Serum level of specific IgG antibody for N and S antigens

Timepoint

One month after training

Method of measurement

Eliza method

Intervention groups

1

Description

Intervention group: patients in this group, in addition to drug treatment according to the national guidelines for the new coronavirus, They receive saffron supplements for 14 days. (400 mg equivalent to 5.7 mg per kilogram of body weight per day)

Category

Treatment - Other

2

Description

Control group: Patients in this group receive drug treatment according to the national guidelines for the new coronavirus.

Category

Placebo

3

Description

Intervention group: Patients in this group, in addition to the medical treatment according to the national guidelines for the new coronavirus, two weeks of endurance exercise (12 sessions 2 hours, four sessions per week, aerobic exercise with an intensity of 65% of the maximum heart rate).

Category

Treatment - Other

4

Description

Intervention group: Patients in this group receive saffron supplement for 14 days, in addition to the medical treatment according to the national guidelines for the new coronavirus. (400 mg equal to 5.7 mg per kilogram of body weight per day) plus two weeks of endurance training (12 sessions 2 hours, four sessions per week,

aerobic exercise with an intensity of 65% of maximum heart rate).

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Koshksaray Health Center

Full name of responsible person

Mohammad Taheri

Street address

Koshksaray, Qaraje Mohammad Road

City

Koshksaray

Province

East Azarbaijan

Postal code

5447134581

Phone

+98 41 4214 0499

Email

fateme.halalkhor@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

The University of Mohaghegh Ardabili

Full name of responsible person

Vice President of Research and Technology of Mohaghegh Ardabili University

Street address

university street

City

Ardabil

Province

Ardabil

Postal code

5619911367

Phone

+98 45 3150 0000

Email

info@uma.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

The University of Mohaghegh Ardabili

Proportion provided by this source

1

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**

University of Tabriz

Full name of responsible person

Fateme Halalkhor

Position

MSc. Student in Sport Nutrition, University of Tabriz

Latest degree

Master

Other areas of specialty/work

Traditional Medicine

Street address

Faculty of Physical Education and Sport Sciences,
University of Tabriz, 29 Bahman BLVD, Tabriz, East
Azarbaijan

City

Tabriz

Province

East Azarbaijan

Postal code

5447135411

Phone

+98 41 4224 1099

Fax**Email**

fateme.halalkhor@gmail.com

Person responsible for scientific inquiries**Contact****Name of organization / entity**

University of Tabriz

Full name of responsible person

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University of Tabriz

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Fax**Email**

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All data is potentially shareable after de-identifying
individuals

When the data will become available and for how long

After completing the plan

To whom data/document is available

Only for researchers working in academic and scientific
institutions

Under which criteria data/document could be used

For research

From where data/document is obtainable

Email address of the researcher

What processes are involved for a request to access

data/document

Email address of the researcher
Comments