Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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)

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+98 41 4224 1099

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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 sessions2 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
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Koshksaray
Province
East Azarbaijan
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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
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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