Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Investigating the effect of oral supplementation containing jujube and saffron on recovery and controlling the symptoms of patients with covid-19

Protocol summary

Study aim
Investigating the effect of oral supplementation containing jujube and saffron on recovery and controlling the symptoms of patients with covid-19

Design
A clinical trial with control group, parallel groups, double-blind, randomized, phase 2-3 on 60 patients. Random allocation software has used for randomization.

Settings and conduct
Valiasr Hospital, Birjand; After obtaining informed written consent, patients will be randomly divided into 2 groups (placebo and supplement). A standard treatment will be provided for both. The duration of the intervention is 2 weeks and the received dose is equal to 15 ml of the supplement three times a day after each meal orally. Tests and examinations of patients will be performed daily. During the study, with the exception of the pharmacist (who has no role in the clinical study and evaluations), the rest of the project partners, including infectious disease specialists, radiologists, nurses, and project analysts, will not know how the drug and placebo are allocated.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Clinical or paraclinical confirmation of Covid-19; Absence of underlying disease including diabetes, thyroid disorders, cardiovascular, autoimmune, hemorrhagic, and other lung diseases; No pregnancy and lactation. Exclusion criteria: Patients with a severe form of Corona disease (patients under ventilator, patients with oxygen saturation percentage below 88 mm Hg, and patients admitted to the ICU), Patient's unwillingness to continue the project; Sensitivity to the components of supplement.

Intervention groups
Intervention group includes patients with Corona who receive supplements containing jujube and saffron. Comparison group includes patients with Corona who receive placebo intervention.

Main outcome variables
radiological changes, duration of hospitalization, body temperature, cough rate, CBC indices

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20160305026917N2**
Registration date: **2021-05-25, 1400/03/04**
Registration timing: **prospective**

Last update: **2021-05-25, 1400/03/04**
Update count: **0**

Registration date
2021-05-25, 1400/03/04

Registrant information

Name
Sayyedeh Fatemeh Askari

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 56 3238 1919

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-07-21, 1400/04/30

Expected recruitment end date
2022-01-20, 1400/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of oral supplementation containing jujube and saffron on recovery and controlling the symptoms of patients with covid-19

Public title

The effect of jujube and saffron supplement on Covid-19

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Clinical or paraclinical confirmation of disease Absence of underlying disease including diabetes, thyroid disorders, cardiovascular, autoimmune, and hemorrhagic and other lung diseases No pregnancy and breastfeeding.

Exclusion criteria:

Patients with severe forms of the disease (patients under ventilator, patients with oxygen saturation below 88 mm Hg, and patients admitted to the ICU The patient's unwillingness to continue participating in the project Sensitivity to the components of the supplement.

Age

From **15 years** old to **70 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomized double-blind controlled clinical trial randomization using random allocation software According to the randomization, each supplement or placebo sample is assigned a number and the patient will not be informed about taking the drug or placebo (Numbers from 1 to 60).

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients will be notified to participate in the study and obtaining a consent form but they will be blind to the supplements or placebo. During the study, with the exception of the pharmacist (who has no role in the clinical study and evaluations), the rest of the project partners, including infectious disease specialists, radiologists, nurses, and project analysts, will not know how the drug and placebo are allocated. Supplement and placebo are also identical in appearance so that they are not recognizable to patients.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Birjand University of Medical Sciences

Street address

Ghaffari Ave.

City

Birjand

Province

South Khorasan

Postal code

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Approval date

2021-05-17, 1400/02/27

Ethics committee reference number

IR.BUMS.REC.1400.054

Health conditions studied

1

Description of health condition studied

Covid-19

ICD-10 code

U07.1

ICD-10 code description

Covid-19

Primary outcomes

1

Description

Investigation of radiological changes

Timepoint

0 (before the intervention), 7th, 14th day after intervention

Method of measurement

Computed tomography scan

2

Description

Coughing

Timepoint

0 (before the start of the intervention) - 14th day after

intervention

Method of measurement

Based on Visual Analogue Scale

3

Description

Complete blood count indices

Timepoint

0 (before the intervention), 7th, 14th day after intervention

Method of measurement

Complete blood count test

Secondary outcomes

1

Description

Duration of hospitalization

Timepoint

After the patient is discharged

Method of measurement

The number of days of hospitalization

2

Description

Body temperature

Timepoint

0 (before the start of the intervention) - 14th day after intervention

Method of measurement

Thermometer

Intervention groups

1

Description

Intervention group: Standard treatment will be performed and a saffron-jujube supplement will be prescribed with it for 30 patients. The duration of the intervention is 2 weeks and the received dose is equal to 15 ml of the supplement three times a day after each meal orally. On the zero-day, during consumption, and on the 7th and 14th days of the intervention, the relevant variables are measured.

Category

Treatment - Drugs

2

Description

Control group: Standard treatment will be performed and placebo will be prescribed with it for 30 patients. The placebo does not contain saffron and jujube. The duration of the intervention is 2 weeks and the received dose is equal to 15 ml of the supplement three times a day after each meal orally. On the zero-day, during consumption, and on the 7th and 14th days of the intervention, the relevant variables are measured.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Valiasr Hospital, Birjand

Full name of responsible person

Sayyedeh Fatemeh Askari

Street address

Ghaffari Ave.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Birjand University of Medical Sciences

Full name of responsible person

Toba kazemi

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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

Birjand University of Medical Sciences

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
Birjand University of Medical Sciences
Full name of responsible person
Sayyedeh Fatemeh Askari
Position
Assistant professor
Latest degree
Ph.D.
Other areas of specialty/work
Phytopharmaceuticals
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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