

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jun 2026

Effect of Opontia Cactus extract on improving pulmonary and clinical function in patients with Covid-19

Protocol summary

Study aim

Determining the effect of Opuntia cactus extract on improving blood oxygenation, shortening the length of hospital stay, improving headaches, reducing myalgia and shortening the period of weakness and lethargy of patients

Design

Matched clinical trial with control group, double blinded

Settings and conduct

In this double blind randomized clinical trial with parallel design, 48 patients with moderate Covid-19 severity inpatients in Imam Ali hospital will be allocated to intervention or standard treatment using balanced block randomization method.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Lung CT scan or PCR are appropriate for Covid-19 disease Age 18 to 60 years The oxygen saturation more than 90% Exclusion criteria: Taking supplements Receiving mechanical ventilation Multi organ failure

Intervention groups

Twenty-four patients will receive 250 cc syrup of Opuntia cactus daily, for 7 days in the morning, and another 24 patients in control group will receive 250 cc syrup of apple extract. Shortness of breath, body aches, headaches, weakness, venous blood oxygen and body temperature will be checked.

Main outcome variables

Improving pulmonary function, measured by measuring venous blood oxygen: Improving clinical performance by following the patient's clinical symptoms such as body temperature, body aches, cough, shortness of breath, headache, and weakness.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200504047298N2**

Registration date: **2020-06-15, 1399/03/26**

Registration timing: **prospective**

Last update: **2020-06-15, 1399/03/26**

Update count: **0**

Registration date

2020-06-15, 1399/03/26

Registrant information

Name

Zeinab Siami

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 4602 2136

Email address

z.siami@abzums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-07-10, 1399/04/20

Expected recruitment end date

2020-07-26, 1399/05/05

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Opontia Cactus extract on improving pulmonary and clinical function in patients with Covid-19

Public title

Effect of Opuntia Cactus extract in patients with Covid-19

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Patients who have CT scan or PCR data in accordance with Covid-19 Patients aged 18 to 60 years Patients who have not hypoxemia (oxygen saturation more than 90%)

Exclusion criteria:

Patients who taking herbal supplements are excluded Patients who were receiving mechanical ventilation or extracorporeal membrane oxygenation (ECMO) , are excluded Patients with signs of multiorgan failure at screening (Exclusion criteria included alanine aminotransferase (ALT) or aspartate aminotransferase (AST) levels greater than 5 times the upper limit of the normal range or estimated creatinine clearance of less than 50 ml per minute (by the Cockcroft-Gault formula)) are excluded

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **48**

Randomization (investigator's opinion)

Randomized

Randomization description

In the current study, patients were randomly allocated into two groups of intervention and conventional treatment by balanced block randomization technique with 4 blocks.R software generated random numbers chains 1 to 6 until the desired sample size was achieved. Preparation of sequences of random allocation of cases and putting them in sealed envelopes (airtight) and numbered with a five-digit serial number were performed by a third person who was not involved in the study design.

Blinding (investigator's opinion)

Double blinded

Blinding description

The treatment group is given a glass of cactus opuntia syrup and the control group is replaced by a syrup of apple extract in a simmlar colour and same glass. Whoever is given cactus syrup and who is given placebo syrup is considered to be blind for the patient and the researcher. So the patients and the researcher are in no way aware of the division of the control and medication group and receive their treatment and care process according to the country's guideline treatment.

Placebo

Used

Assignment

Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Alborz University of Medical Sciences

Street address

Emam Ali Hospital, Azimeyeh, Karaj

City

Karaj

Province

Alborz

Postal code

3154686695

Approval date

2020-05-01, 1399/02/12

Ethics committee reference number

IR.ABZUMS.REC.1399.024

Health conditions studied

1

Description of health condition studied

Covid-19

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Improving lung function

Timepoint

Before starting the intervention, Up to 14 days daily after starting the intervention

Method of measurement

Measurement of venous blood Oxygen

Secondary outcomes

1

Description

Improving clinical performance

Timepoint

Before starting the intervention, Up to 14 days after starting the intervention

Method of measurement

Clinical symptoms include cough, shortness of breath, body aches, headaches, weakness, and body temperature are examined daily.

Intervention groups

1

Description

Intervention group: Cactus Opuntia is purchased from a reputable greenhouse in the form of cactus leaves and is extracted by the extraction machine in 250 cc bottles and is brought to the hospital daily for patients. In addition to standard treatment based on national guidelines, cactus extract 250 cc daily is given daily in the morning for 7 days and the patient is followed up for the next 7 days.

Category

Treatment - Other

2

Description

Control group: Control group: In this group, in addition to standard treatment based on national guidelines, 250 cc of aloe vera syrup is given daily.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Ali hospital

Full name of responsible person

Zeinab Siami

Street address

Emam Ali hospital, Azimeyeh, Karaj

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+98 26 3252 7576

Email

z.siami@abzums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Karaj University of Medical Sciences

Full name of responsible person

Mohammad Noorisepehr

Street address

Deputy of Research and Technology, Saffarian Alley, Golshahr

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Karaj

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Alborz

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3198764653

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Research@abzums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Karaj 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

Karaj University of Medical Sciences

Full name of responsible person

Zeinab Siami

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Infectious diseases

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Karaj University of Medical Sciences

Full name of responsible person

Zeinab Siami

Position

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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

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

Patient data will be published in average numbers not as a distinct ones.

When the data will become available and for how long

Access starts 6 months after printing results

To whom data/document is available

The data will be available to researchers working at academic and scientific institutions and industries

Under which criteria data/document could be used

No other conditions are allowed for the use of data and documentation

From where data/document is obtainable

z.siami@abzums.ac.ir

What processes are involved for a request to access data/document

The data will be sent via email no later than one month after the request.

Comments**Person responsible for updating data****Contact****Name of organization / entity**

Karaj University of Medical Sciences

Full name of responsible person

Zeinab Siami

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Infectious diseases

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