Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Oct 2026

Efficacy of Palm Leaf Extract (Phoenix dactylifera) in Patients with COVID-19 Patients Admitted to Ganjavian Hospital in Dezful with Mild to Moderate Stages: A Randomized Clinical Trial

Protocol summary

Study aim

Efficacy of Palm Leaf Extract (Phoenix dactylifera) in Patients with New Coronavirus (COVID-19) in Weak to Moderate Stages.

Design

100 patients who will be randomly assigned to two groups of 50 people (intervention group and control group) will be selected from patients referred to Ganjavian hospital who will be diagnosed by the physician at the initial visit of COVID-19 and volunteer to participate in the project.

Settings and conduct

This study was a double-blind randomized controlled clinical trial. The physician, nurses and the volunteer patient are not aware of the type of prescribed drug. 100 (men and women of different ages) from patients with COVID-19, referred to Ganjuyan Hospital in Dezful who are in mild or moderate stage, will be selected.

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients >12 years of age (male/female) with mild to moderate disease, which can be determined by clinical criteria (dry cough, fever and dyspepsia) and para clinical indices (PaO2, PCR, CT Scan, CRP, CBC) with COVID-19; signing consent by persons or the assistant of patients. Exclusion criteria: dissatisfaction of patients or patients' assistants; allergic reactions from the use of palm extract; critically ill patients or cases where the doctor may not recommend the use of intervention.

Intervention groups

Patients in the intervention groups take 5 ml of Phoenix (solution containing palm leaf extract) 5 times a day. Patients in the control groups take 5 ml of Phoenix placebo (solution without palm leaf extract) 5 times a day.

Main outcome variables

Palm Leaf Extract CT scan Body temperature CRP PCR PaO2 ESR White Blood Cell Count

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201015049036N1**
Registration date: **2020-11-27, 1399/09/07**
Registration timing: **retrospective**

Last update: **2020-11-27, 1399/09/07**
Update count: **0**

Registration date

2020-11-27, 1399/09/07

Registrant information

Name

Mohammad Dorchin

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 4255 6011

Email address

dr.dorchin@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-09-12, 1399/06/22

Expected recruitment end date

2020-11-12, 1399/08/22

Actual recruitment start date

2020-09-18, 1399/06/28

Actual recruitment end date

2020-11-16, 1399/08/26

Trial completion date
2020-11-16, 1399/08/26

Scientific title
Efficacy of Palm Leaf Extract (Phoenix dactylifera) in Patients with COVID-19 Patients Admitted to Ganjavian Hospital in Dezful with Mild to Moderate Stages: A Randomized Clinical Trial

Public title
Efficacy of Date Palm Leaf Extract (Phoenix dactylifera) in Patients with COVID-19 Hospitalized in Ganjavian Hospital in Dezful

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients >12 years of age (male/female) with mild to moderate disease, which can be determined by clinical criteria (dry cough, fever and dyspnea) and paraclinical indices PO2, PCR, CT Scan, CRP, CBC Signing the form of consent by persons >18 years of age or the guardians of the under-aged patients

Exclusion criteria:
Dissatisfaction of patients or the patients' guardians Any allergic reactions from the use of the palm extract Critically ill patients or the cases where the physician in chief may not recommend this intervention for hospitalized patients

Age
From **12 years** old to **80 years** old

Gender
Both

Phase
2

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **100**
Actual sample size reached: **100**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients with inclusion criteria and with respect to their genders will be assessed clinically. The patients will be divided into to two groups randomly: drug recipients and placebo recipients. The patients will be assigned certain codes, and only the pharmacy team will be aware of the nature of the two groups. The physician in chief, the nurses and the patients are not aware of whether they are receiving drug or placebo.placebo of the syrup.

Blinding (investigator's opinion)
Double blinded

Blinding description
Patients use drugs and placebo that are in exactly the same containers and labels but have different codes, and except for the pharmacy team, none of the treating physicians, nurses, and patients are aware of those codes.

Placebo
Used

Assignment
Parallel

Other design features
The study will be conducted in cooperation with infectious and internal specialists and pulmonary specialists.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee Dezful University of Medical Sciences

Street address
Vice Chancellor for rsearch, Dezful University of Medical Sciences, Azadegan alley, Andimeshk road to Dezful

City
Dezful

Province
Khouzestan

Postal code
6461643993

Approval date
2020-10-06, 1399/07/15

Ethics committee reference number
IR.DUMS.REC.1399.037

Health conditions studied

1

Description of health condition studied
Coronavirous (COVID19)

ICD-10 code
U07.1

ICD-10 code description
Corona virus infection, unspecified

Primary outcomes

1

Description
Lung infection

Timepoint
At the beginning of entering the plan, at the end of the first week of treatment and at the end of the second week of treatment

Method of measurement
CT Scan

2

Description
Virus diagnosis
Timepoint
At the beginning of entering the plan, at the end of the first week of treatment and at the end of the second week of treatment
Method of measurement
PCR

3

Description
Fever
Timepoint
At the beginning of entering the plan, at the end of the first week of treatment and at the end of the second week of treatment
Method of measurement
Thermometer

4

Description
PaO2: oxygen pressure in arterial blood
Timepoint
At the beginning of entering the plan, at the end of the first week of treatment and at the end of the second week of treatment
Method of measurement
Record the degree of oxygen pressure

5

Description
CRP: reactive protein in blood for detect the inflammation
Timepoint
At the beginning of entering the plan, at the end of the first week of treatment and at the end of the second week of treatment
Method of measurement
Comparison with normal standard range in blood test

6

Description
ESR: erythrocyte sedimentation rate used to monitor inflammatory diseases
Timepoint
At the beginning of entering the plan, at the end of the first week of treatment and at the end of the second week of treatment
Method of measurement
Comparison with normal standard range in blood test

7

Description
WBC: white blood cell
Timepoint
At the beginning of entering the plan, at the end of the first week of treatment and at the end of the second week of treatment
Method of measurement
Comparison with normal standard range in blood test

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: treatment- medicine: Phoenix medicine (contains hydro alcoholic solution, Phoenix leaf extract, Vitamin C and Strawberry flavoring) 5 times/day, each time 5 ml.
Category
Treatment - Drugs

2

Description
Control group: treatment-placebo: contains hydro alcoholic solution, Vitamin C , Strawberry flavoring, without Phoenix leaf extract) 5 times/day, each time 5 ml.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Ganjavian Hospital
Full name of responsible person
Mohammad Dorchin
Street address
Gangavian Hospital, Andimesh road to Dezful
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6461643981
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bbd@dums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Dezfoul University of Medical Sciences
Full name of responsible person

Dr. Maysam Mard Soltani

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Vice Chancellor for Research, Dezful University of Medical Sciences

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research@dums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
University

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
Persons

Person responsible for general inquiries

Contact

Name of organization / entity
Dezfoul University of Medical Sciences

Full name of responsible person
Mohammad Dorchin

Position
Physician

Latest degree
Specialist

Other areas of specialty/work
Radiotherapy

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Person responsible for updating data

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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

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

Title and more details about the data/document

The data will be collected by an epidemiologist's cooperation after the jamming.

When the data will become available and for how long

Two months.

To whom data/document is available

Dr Gholamreza Amin , Ghasem Takdehghan؛ Dr. Mohammad Dorchin

Under which criteria data/document could be used

Only for data collection and analysis.

From where data/document is obtainable

Dr. Mohammad Dorchin

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

Written request and approval of the project's executive and the main colleagues of the project (Dr. Gholamreza Amin and Mr. Ghasem Takdehghan)

Comments