

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

18 Jun 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 Ganjavian 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 (PaO<sub>2</sub>, 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

PaO<sub>2</sub> 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 PO<sub>2</sub>, 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**

PaO<sub>2</sub>: 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

##### **City**

Dezful

##### **Province**

Khouzestan

##### **Postal code**

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##### **Phone**

+98 61 4242 2040

##### **Fax**

+98 61 4242 7159

##### **Email**

bbd@dums.ac.ir

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Dezful University of Medical Sciences

##### **Full name of responsible person**

Dr. Maysam Mard Soltani

**Street address**

Vice Chancellor for Research, Dezful University of  
Medical Sciences

**City**

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**Province**

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**Email**

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

**Street address**

No.440 west Farhang 2 Ave.

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**Province**

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**Postal code**

6461896973

**Phone**

+98 61 4255 6011

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+98 61 4242 7160

**Email**

dr.dorchin@gmail.com

**Person responsible for scientific  
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**

**Contact**

**Name of organization / entity**

Dezfoul University of Medical Sciences

**Full name of responsible person**

Mohammad Dorchin

**Position**

Assistant professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Radiotherapy

**Street address**

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**Fax**

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**Email**

dr.dorchin@gmail.com

**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**