

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 Jun 2026

### Comparison of the effectiveness of oral syrup and intranasal spray of *Falcaria Vulgaris* plant on patients with Covid-19

#### Protocol summary

##### Study aim

Evaluation of the effectiveness of oral syrup and nasal spray of Ghaziani plant on the symptoms of patients with COVID-19

##### Design

This phase 3 clinical trial is performed in a double-blind method on 100 patients with Covid 19 virus. 100 patients are randomly assigned to 50 blocks including 2 patients. Then each of the 2 patients in the block of herbal medicine or placebo with code A or B receives, so that 50 people are assigned herbal medicine and 50 people are placebo. The duration of treatment is one week.

##### Settings and conduct

100 patients with Covid virus 19 referred to Farabi and Golestan hospitals in Kermanshah has entry conditions, selected and randomly divided into two groups. These patients are cared by a trained nurse and the amount of spo2 and the progress of patients in both groups is recorded daily for a week. The identification code is recorded .The physician, nurse, patient, data collector, and person evaluating the outcome are unaware of the medication and placebo group. Only the project manager know the type of groups.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with Covid virus 19 aged 20 to 70 years. Exclusion criteria: 1- Pregnant women 2- Children 3- Elderly (people over 70 years old) 4- People who use mechanical ventilation 5- People who are undergoing chemotherapy 6- People who receive corticosteroid pulse

##### Intervention groups

Intervention group: Patients in this group use syrup and nasal spray prepared from mountain ghaziani plant, which is dried under normal conditions and prepared as a syrup or nasal spray, three times a day for a week. control treatment: Routine treatment according to the latest update of the new national coronavirus treatment guidelines

##### Main outcome variables

blood oxygen saturation; temperature; Number of breaths;dyspnea ; Cough; Rate of lung involvement

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20130722014106N9**

Registration date: **2021-11-30, 1400/09/09**

Registration timing: **registered\_while\_recruiting**

Last update: **2021-11-30, 1400/09/09**

Update count: **0**

##### Registration date

2021-11-30, 1400/09/09

##### Registrant information

##### Name

Reza Tahvilian

##### Name of organization / entity

Kermanshah University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 83 1427 6482

##### Email address

rtahvilian@kums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-11-22, 1400/09/01

##### Expected recruitment end date

2021-12-21, 1400/09/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**  
empty

**Scientific title**  
Comparison of the effectiveness of oral syrup and intranasal spray of Falcaria Vulgaris plant on patients with Covid-19

**Public title**  
Effect of oral syrup and intranasal spray of Falcaria Vulgaris plant in patients with Covid-19

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Confirmation of coronavirus infection by CT scan of the chest and PCR test Age 20 to 70 years Willingness to cooperate in the study and completion of informed written consent  
**Exclusion criteria:**  
pregnant women children Elderly (people over 70) People who use mechanical ventilation People undergoing chemotherapy People who receive corticosteroids are excluded from the study

**Age**  
From **20 years** old to **70 years** old

**Gender**  
Both

**Phase**  
3

**Groups that have been masked**

- Participant
- Care provider
- Outcome assessor
- Data and Safety Monitoring Board

**Sample size**  
Target sample size: **100**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
Using random blocking method (Block Randomization ) with 4 blocks and a ratio of 1: 1 are allocated to the treatment and control groups. (For 4 blocks there will be six different modes: 1.TTCC 2.TCTC 3.TCCT 4.CCTT 5.CTTC 6.CTCT). Random numbers will be created with the help of a computer and a statistics consultant. For numbers between 0 and 1.6, combination 1 (TTCC), numbers between 1.6 and 2.6, combination 2 (TCTC), etc. are divided into two groups of 50 people. Patients based on randomized block allocation method classified according to age range (20 years and later) and gender (male, female) in two groups with 50 people (25 males and 25 females) with Herbal medicine treatment (treatment) and routine treatment (control).

**Blinding (investigator's opinion)**  
Double blinded

**Blinding description**  
Herbal medicine and placebo packaging is prepared with a label with code B or A. Other specifications on the labels are the same. Physicians, nurses, patients, data

collectors, and those evaluating the outcome are unaware of the drug and placebo group. Patients are aware that they are in either the herbal group or the placebo group, but they do not know the type of group they are in.

**Placebo**  
Used

**Assignment**  
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Kermanshah University of Medical Science

##### Street address

Central building, Beheshti Blvd, Kermanshah University of Medical Science

##### City

Kermanshah

##### Province

Kermanshah

##### Postal code

6715847141

#### Approval date

2021-10-19, 1400/07/27

#### Ethics committee reference number

IR.KUMS.REC.1400.544

## 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

Blood oxygen saturation

#### Timepoint

At the beginning and end of the study on a regular basis

#### Method of measurement

Pulse oximeter

### 2

#### Description

Rate of lung involvement

**Timepoint**

beginning and end of the study

**Method of measurement**

computed tomography scan

**Secondary outcomes**

1

**Description**

Number of breaths

**Timepoint**

At the beginning and end of the study on a regular basis

**Method of measurement**

Counting breaths per minute

2

**Description**

Body temperature

**Timepoint**

At the beginning and end of the study on a regular basis

**Method of measurement**

thermometer and clinical examination

3

**Description**

dyspnea

**Timepoint**

At the beginning and end of the study on a regular basis

**Method of measurement**

clinical examination

4

**Description**

cough

**Timepoint**

At the beginning and end of the study on a regular basis

**Method of measurement**

clinical examination

**Intervention groups**

1

**Description**

Intervention group: Patients in this group, in addition to receiving standard medications, use a syrup or nasal spray prepared from the mountain ghaziani plant, which is dried under normal conditions and prepared as a syrup and nasal spray three times a day for a week.

**Category**

Treatment - Drugs

2

**Description**

Control group: Routine treatment according to the latest update of the new national coronavirus treatment

guidelines

**Category**

Treatment - Drugs

**Recruitment centers**

1

**Recruitment center**

**Name of recruitment center**

Farabi Hospital

**Full name of responsible person**

Hossein Amiri

**Street address**

Dowlatabad Blvd, Farabi Hospital, Kermanshah Province, Kermanshah

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**Phone**

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hossein.amirii@yahoo.com

**Sponsors / Funding sources**

1

**Sponsor**

**Name of organization / entity**

Kermanshah University of Medical Sciences

**Full name of responsible person**

Reza KhodaRahmi

**Street address**

Shahid Beheshti Blvd., Kermanshah University of Medical Sciences

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rkhodarahmi@mbrc.ac.ir

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Kermanshah 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**

Kermanshah University of Medical Sciences

**Full name of responsible person**

Hossein Amiri

**Position**

Non-faculty specialist physician

**Latest degree**

Specialist

**Other areas of specialty/work**

Internal Medicine

**Street address**

Naghlieh Street - Imam Khomeini Hospital,  
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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Kermanshah University of Medical Sciences

**Full name of responsible person**

Hossein Amiri

**Position**

Non-faculty specialist physician

**Latest degree**

Specialist

**Other areas of specialty/work**

Internal Medicine

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**Postal code**

6718743161

**Phone**

008337272049

**Email**

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

Kermanshah University of Medical Sciences

**Full name of responsible person**

Reza Tahvilian

**Position**

Associate Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Medical Pharmacy

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**Phone**

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**Email**

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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**

No - There is not a plan to make this available

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

No - There is not a plan to make this available

**Analytic Code**

No - There is not a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available

**Title and more details about the data/document**

The main consequences are shared after the intervention in the disease

**When the data will become available and for how long**

One year after the publication of the results

**To whom data/document is available**

Researchers, doctors and students

**Under which criteria data/document could be used**

For the use of other researchers

**From where data/document is obtainable**

Correspond with the project manager. Phone:  
08337272049 Email: hossein.amirii@yahoo.com

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

Request via email

**Comments**