Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Nov 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

City

kermanshah

Province

Kermanshah

Postal code

67198 51151

Phone

+98 83 3727 2049

Email

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

City

kermanshah

Province

Kermanshah

Postal code

6715847141

Phone

+98 83 3838 4185

Email

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, Kermanshah
City
kermanshah
Province
Kermanshah
Postal code
6718743161
Phone
008337272049
Email
hossein.amirii@yahoo.com

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
Street address
Naghlieh Street - Imam Khomeini Hospital, Kermanshah
City
kermanshah
Province
Kermanshah
Postal code
6718743161
Phone
008337272049
Email
hossein.amirii@yahoo.com

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
Street address
University Street, Parstar Blvd.
City
kermanshah
Province
Kermanshah
Postal code
6714415153
Phone
+98 83 3427 6480
Email
rtahvilian@kums.ac.ir

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