

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

Effect of Dinvl medicinal herb on improving of clinical and paraclinical symptoms in patients with COVID-19 :A Randomized Controlled Trial

Protocol summary

Study aim

Evaluation the effect of Dinol herbal medicine on the improvement of clinical and paraclinical symptoms in hospitalized patients with COVID-19

Design

A randomized controlled, triple blinded clinical trial with a parallel-group design of 80 patients, which participants will be allocated into trial groups using Random Allocation Software (RAS)

Settings and conduct

This study is a randomized controlled triple blinded trial that will be conducted on COVID-19 patients who referred to 29 Bahman Hospital of Tabriz in two groups (intervention and control groups). The patients, researcher, monitoring committee, and statistical analyst will be blind to the received active drug or placebo. Participants will be allocated into trial groups randomly using Random Allocation Software (RAS). Patients will receive a sealed matte containers of Dinvl or placebo by giving 2 sublingual tablets every 6 hours for 7 days. Random allocation sequences will be generated by the non-involved person in the research. Both groups will receive routine treatments.

Participants/Inclusion and exclusion criteria

Patients aged 15 years and older with COVID-19 who had newly hospitalized; Having a definite disease; Having a signed informed consent form to participate in the study; and not participation in another clinical trial simultaneously.

Intervention groups

In the intervention group, participants will receive two 399 ± 5 mg sublingual Dinvl tablets containing 43.5 mg of herbal powder every 6 hours for 6 days (a total of 56 tablets per person) non-simultaneous with any other medications. The control group will receive a placebo, resembled Dinvl tablets with the same prescription. Both groups will receive routine treatments.

Main outcome variables

Respiratory Rate (RR); Oxygen saturation (SpO₂); Serum

white blood cell count; serum CRP level; ESR; the number of hospitalization days; Mortality

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200518047497N2**

Registration date: **2020-06-06, 1399/03/17**

Registration timing: **prospective**

Last update: **2020-06-06, 1399/03/17**

Update count: **0**

Registration date

2020-06-06, 1399/03/17

Registrant information

Name

Javad Amadian Heris

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 41 3333 9151

Email address

ahmadianj@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-06-20, 1399/03/31

Expected recruitment end date

2020-08-20, 1399/05/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Dinvl medicinal herb on improving of clinical and paraclinical symptoms in patients with COVID-19 :A Randomized Controlled Trial

Public title

Effect of Dinvl on improving of clinical and paraclinical symptoms in patients with COVID-19

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

COVID-19 patients aged 15 years and older who newly admitted (first day of hospitalization) Having definite COVID-19 disease Obtaining informed consent to participate in the trial Non-participation in another clinical trial simultaneously

Exclusion criteria:

Epilepsy Having liver or renal failure according to the patient's statement, physician examination or based on creatinine, SGOT, SGPT, LDH tests. Immunodeficiency (treated with Corticosteroids over 12.5 mg / d Prednisolone for more than two weeks, chemotherapy, malignancies, organ transplants, HIV patients, other viral diseases. Having other infectious diseases according to the diagnosis of the physician and the information of medical record. Pregnancy (according to the patient's statement and examination by a physician). Breastfeeding (according to the patient's statement).

Age

From 15 years old

Gender

Both

Phase

3

Groups that have been masked

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

Sample size

Target sample size: 80

Randomization (investigator's opinion)

Randomized

Randomization description

Participants will be allocated to trial groups (intervention and placebo groups) randomly using Random Allocation Software (RAS) through random block sizes of 4 and 6 with an allocation ratio of 1:1. Patients will receive a sealed containers of Dinvl sublingual tablets 399 ± 5 mg containing 43.5 mg of herbal powder or placebo made by Zahravi Pharmaceutical Company of Tabriz. Two sublingual tablets will be taken every 6 hour for 7 days (a total of 56 tablets for each person) not simultaneously with other any medications. Random sequencing allocation will be produced by the person who has not to

participate in the research. Containers will be numbered from 1 to 80 according to the sequence generated. Both groups will receive routine treatments.

Blinding (investigator's opinion)

Triple blinded

Blinding description

This study is a randomized controlled triple-blind clinical trial. This means that patient, researcher, safety and data monitoring committee, clinical caregiver and statistical analyst will be blind to the received medication. Each person will be given a opaque matte container of medicine containing herbal tablets of Dinolol or placebo in the identical shape, weight, smell and color.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Tabriz University of Medical Sciences

Street address

No 2 Central Building, Tabriz University of Medical Sciences, University Street, Tabriz

City

Tabriz

Province

East Azarbaijan

Postal code

5165665931

Approval date

2020-05-10, 1399/02/21

Ethics committee reference number

IR.TBZMED.REC.1399.135

Health conditions studied**1****Description of health condition studied**

COVID-19

ICD-10 code

U07.01

ICD-10 code description

Novel Coronavirus Disease (COVID-19)

Primary outcomes**1****Description**

Respiratory Rate
Timepoint
Daily
Method of measurement
Observation

2
Description
Oxygen saturation (SpO2)
Timepoint
Daily
Method of measurement
Pulse Oximeter

3
Description
Serum White Blood Cell count
Timepoint
Before- 14 days after intervention
Method of measurement
Laboratory cell counter

4
Description
Serum CRP level
Timepoint
Before- 14 days after intervention
Method of measurement
Biochemical method

5
Description
ESR (Erythrocyte Sedimentation Rate)
Timepoint
Before- 14 days after intervention
Method of measurement
Checking the sedimentation rate of erythrocytes in a special tube within one hour

6
Description
Number of hospitalization days
Timepoint
After intervention
Method of measurement
Questionnaire

7
Description
Mortality
Timepoint
Daily
Method of measurement
Questionnaire

Secondary outcomes

1
Description
The time of absence of dry Cough
Timepoint
Daily
Method of measurement
Daily symptom recording questionnaire

2
Description
The time of absence of trembling
Timepoint
Daily
Method of measurement
Daily symptom recording questionnaire

3
Description
The time of absence of sore throat
Timepoint
Daily
Method of measurement
Daily symptom recording questionnaire

4
Description
The time of absence of dry Cough
Timepoint
Daily
Method of measurement
Daily symptom recording questionnaire

5
Description
The time of absence of difficulty in breathing or shortness of breath
Timepoint
Daily
Method of measurement
Daily symptom recording questionnaire

6
Description
The time of absence of temperature equal to or grater than 37.8 C
Timepoint
Daily
Method of measurement
Daily symptom recording questionnaire

7
Description
Body temperature
Timepoint

Daily
Method of measurement
Thermometer

8

Description
Side effects
Timepoint
Daily
Method of measurement
Side effects checklist

Intervention groups

1

Description
Intervention group: In the intervention group, participants will receive Dinvl sublingual tablets 399±5 mg containing 43.5 mg of herbal powder made by Zahravi Pharmaceutical Company in Tabriz which will be taken every 6 hours for 7 days (a total of 56 tablets per person) not at the same time with other drugs. Both groups will receive routine treatments.
Category
Treatment - Drugs

2

Description
Control group: The control group will receive a placebo, resembled the Dinvl tablets with the same prescription. Both groups will receive routine treatments.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
29 Bahman Hospital
Full name of responsible person
Javad Ahmadian Heris
Street address
29 bahman Boulevard., Tabriz., East Azerbaijan Province
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5166617894
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Zahravi Pharmaceutical Company
Full name of responsible person
Hamed Hamishekar
Street address
Serum Daroo street., 19 km of Tabriz-Tehran road., Tabriz,
City
Tabriz
Province
East Azarbaijan
Postal code
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Phone
+98 41 3630 9401
Fax
+98 41 3630 9400
Email
info@zahravipharma.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Zahravi Pharmaceutical Company
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
Industry

Person responsible for general inquiries

Contact
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Javad Ahmadian Heris
Position
Professor assistant of allergy and clinical immunology
Latest degree
Subspecialist
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Person responsible for scientific inquiries

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Person responsible for updating data

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Golgasht Street, Imam Reza Hospital, Ground Floor,
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

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

Statistical Analysis Plan

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

Informed Consent Form

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

Clinical Study Report

Undecided - It is not yet known if there will be 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

Effect of Dinvl medicinal herb on improving of clinical and paraclinical symptoms in patients with COVID-19 :A Randomized Controlled Trial

When the data will become available and for how long

End of august

To whom data/document is available

healthcare professional- academic members of universities

Under which criteria data/document could be used

An official request from the organization

From where data/document is obtainable

Tabriz University of Medical Sciences

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

Request to Vice-Chancellor for Research and Technology Affairs

Comments