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 Ḍinvl 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 Ḍinvl 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
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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) trough 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 Cronavirus 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

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29 bahman Boulevard., Tabriz., East Azerbaijan Province

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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,

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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

Other areas of specialty/work

Pediatrics

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Person responsible for scientific inquiries

Contact
Name of organization / entity
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Full name of responsible person
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Professor assistant of allergy and clinical immunology
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Person responsible for updating data

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Full name of responsible person
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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- ācademic 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