

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jun 2026

Evaluation effects of DINVL herbal medicine on the recovery of patients with COVID - 19

Protocol summary

Study aim

Evaluation of the time to clinical recovery in the case with Dinvl in moderate-intensity pneumonia caused by Corona 19 compared with the control group

Design

Randomized single blind, phase 3 clinical trial on 60 patients, The random number table was used for randomization

Settings and conduct

This study was performed in hospitals, Baqiat Allah, in Tehran, on patients with moderate-intensity pneumonia caused by covid 19.

Participants/Inclusion and exclusion criteria

Inclusion criteria up18 year-olds with moderate-intensity pneumonia caused by Covid 19 whose disease has been proven on the basis of CT scan or PCR evidence and have signed a participation form. Exclusion criteria All people who are prohibited from taking Dinvl or similar compounds or who are likely to have severe side effects if taken Dinvl.

Intervention groups

Patients with inclusion criteria in the intervention group, in addition to the usual treatment, are treated daily with dinvl for 7 consecutive days. In the control group, the usual treatment for covid 19 infection.

Main outcome variables

Time to clinical recovery 14 days readmission Rate Time to intubation Intubation rate 28 days survival rate side effects caused by dinvl

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200509047373N1**

Registration date: **2020-05-23, 1399/03/03**

Registration timing: **prospective**

Last update: **2020-05-23, 1399/03/03**

Update count: **0**

Registration date

2020-05-23, 1399/03/03

Registrant information

Name

Ahmad Hosseinpour

Name of organization / entity

Health Medicine Chemistry Company

Country

Iran (Islamic Republic of)

Phone

+98 71 3739 1910

Email address

ahosseinpour3@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-06-03, 1399/03/14

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

Evaluation effects of DINVL herbal medicine on the recovery of patients with COVID - 19

Public title

Evaluation effect of Dinvl for Covid19 infection

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients up to 18 years old hospitalized Patient with SpO₂: 85-89% on room air at admission (if correct with nasal O₂ maximum 6 liter/min to SpO₂ ≥ 90) Patients with SpO₂: 90-93% and RR ≥ 30 clinical compatible patients with positive RT-PCR test or consistent HRCT to covid19 pneumonia Sign the study participation form

Exclusion criteria:

Known sensitivity to plant compounds. Pregnant woman
Lactating woman Patients with active peptic.

Age

No age limit

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data and Safety Monitoring Board

Sample size

Target sample size: 60

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, the random number table method is used for randomization. The randomization unit is also the individual. To read numbers, it is also from left to right. For concealment, the method of sequentially numbered, sealed, opaque envelopes is used.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, patients, the main researcher, the physician who visits patients daily for response to the treatment and examination of symptoms, and is responsible for collecting information, and the nursing staff are kept blind to the allocation of study groups. All patients are visited daily by one of the physicians of the treatment team who is in the process of intervention. However, the follow-up of the side effects of the drug and the evaluation of the course of treatment in patients will be performed by another physician, who is also in the general study constant. This physician will monitor the condition of patients at home for up to 4 weeks after discharge and will be completely blind.

Placebo

Not used

Assignment

Parallel

Other design features

In this study, patients with admission conditions were divided into two groups. In addition to the usual treatment for coronavirus infection, the intervention group received Dinvl daily for 7 consecutive days, but the control group received only routine treatment for corona infection .

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Medical Ethics Committee of Baqiyatallah University of Medical Sciences

Street address

Baqiyatallah University of Medical Sciences, Molla Sadra Street

City

Tehran

Province

Tehran

Postal code

1435915371

Approval date

2020-05-09, 1399/02/20

Ethics committee reference number

IR.BMSU.REC.1399.154

Health conditions studied

1

Description of health condition studied

Pneumonia induced by covid19

ICD-10 code

U07.1

ICD-10 code description

COVID-19, virus identified

Primary outcomes

1

Description

Time to clinical recovery

Timepoint

Control clinical signs daily until discharge from the hospital

Method of measurement

Fever control with thermometer, oxygen saturation control with pulse oximetry

Secondary outcomes

1

Description

14 days readmission after discharge.

Timepoint

Up to 14 days after discharge

Method of measurement

All patients will be given a contact number to notify them if they are hospitalized again. All patients will be monitored by phone weekly for up to 4 weeks after the

first day they are admitted.

Intervention groups

1

Description

Intervention group: Dinvl drug, 260 mg each time, 4 times a day for 7 days. Made by Health Medicine Chemistry Company

Category

Treatment - Drugs

2

Description

Control group: Routine tablets is given daily for seven days

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Baqiyatallah Hospital

Full name of responsible person

Mohsen Saberi

Street address

Baqiyatallah Hospital, Molla Sadra Street

City

Tehran

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Phone

+98 21 81261

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Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Health Medicine Chemistry Company

Full name of responsible person

Ahmad Hosseinpour

Street address

No. 256, Alley 7, Peace Boulevard, Skills Square, Shiraz.

City

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Province

Fars

Postal code

7177654547

Phone

+98 71 3739 7910

Email

ahosseinpour3@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Health Medicine Chemistry Company

Proportion provided by this source

100

Public or private sector

Private

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

Health Medicine Chemistry Company

Full name of responsible person

Ahmad Hosseinpour

Position

.

Latest degree

Master

Other areas of specialty/work

Medical Nanotechnology

Street address

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Position

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Latest degree

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Other areas of specialty/work

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

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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

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

Yes - There is a plan to make this available

Title and more details about the data/document

All participants' data is shared after it becomes
unrecognizable

When the data will become available and for how long

Data access starts immediately after printing the results

To whom data/document is available

The data in this study are only available to medical
researchers

Under which criteria data/document could be used

It is available for any analysis or use that aims to
improve and progress in the treatment of covid19
infection

From where data/document is obtainable

Contact email address:ahosseinpour3@gmail.com

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

In case of requesting data for the study, the applicant
must first introduce himself or herself and the relevant
organization to determine the purpose of the data
request and state for what purpose this data is
used. After submitting the request, if the researchers of
this study prove that the data of this study can advance
the therapeutic goals, the information will be sent as
long as the data remains confidential. This process takes
two weeks.

Comments