Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 up18 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 7consecutive 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 pulsoximetry

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:Ḋinvl 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
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1435915371
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+98 21 81261
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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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Fars
Postal code
7177654547
Phone
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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
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Person responsible for updating data

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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:ahisseinpour3@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