Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The effect of Echinacea syrup on outcome in lower respiratory infections in patients with covid-19

Protocol summary

Study aim
Determining the effect of Echinacea syrup on the symptoms of lower respiratory infections in patients with COVID-19

Design
A randomized controlled trial with parallel groups, single-blind, phase 3 on 66 patients. Random numbers method and reading numbers from left to right are used for randomization. A sealed envelope is used to conceal the intervention and control groups.

Settings and conduct
This study was performed in the inpatient wards of Covid-19 patients. All patients who have been definitively diagnosed with Covid-19 by a positive PCR test and who do not have symptoms of lower respiratory infections based on lung imaging, tests, and clinical examinations participate in this study. The intervention group receives Echinacea syrup during the treatment period in the hospital. Data analyzer are kept blind to the information of study groups. The control group receives the usual treatment. Using analytical statistical tests, the effect of treatment results with Echinacea syrup is evaluated.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Definitive diagnosis of Covid's disease 19, willingness to participate, evidence of symptoms of lower respiratory infections; Exclusion criteria: underlying diseases such as COPD, chest deformity

Intervention groups
In the intervention group, the treatment is performed three times a day for three days with 5 cc of Echinacea syrup made by Kimia Daroo factory affiliated to Astan Quds Razavi. In the control group, treatment is performed according to routine inpatient protocols.

Main outcome variables
Symptoms of infection of the lower respiratory tract

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20130522013423N2**
Registration date: **2022-05-18, 1401/02/28**
Registration timing: **registered_while_recruiting**

Last update: **2022-05-18, 1401/02/28**
Update count: **0**

Registration date
2022-05-18, 1401/02/28

Registrant information

Name
Seyed-Mousa mahdizadeh

Name of organization / entity
Faculty of nursing&midwifery mashhad university of medical scienceses

Country
Iran (Islamic Republic of)

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+98 51 3859 1511

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-05-15, 1401/02/25

Expected recruitment end date
2022-10-22, 1401/07/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of Echinacea syrup on outcome in lower

respiratory infections in patients with covid-19

Public title
Evaluation of the effect of Echinacea syrup on outcome in lower of respiratory infections of COVID-19
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Definitive diagnosis of Covid 19 Willingness to participate Evidence of symptoms of lower respiratory infections
Exclusion criteria:
Having underlying diseases such as COPD deformity in the chest
Age
No age limit
Gender
Both

Phase
3
Groups that have been masked

- Data analyser

Sample size
Target sample size: **66**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, a table of random numbers is used for randomization. Numbers are read from left to right. The randomization unit is also individual. For concealment, opaque sealed envelopes with random sequences are used. At the time of sample selection, an envelope is assigned to each patient. Even numbers are considered for the intervention group and odd numbers for the control group.
Blinding (investigator's opinion)
Single blinded
Blinding description
In this single-blind study, data analyzer are blinded to the information of intervention and control groups by assigning an unspecified title (for example, groups 1 and 3).
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Mashhad University of Medical Sciences Ethics
Street address
NO 2, Daneshgah St, Mashhad University of Medical Sciences.
City
Mashhad
Province
Razavi Khorasan
Postal code
13944-91388
Approval date
2022-04-09, 1401/01/20
Ethics committee reference number
IR.MUMS.REC.1401.013

Health conditions studied

1

Description of health condition studied
Covid-19
ICD-10 code
U10.9
ICD-10 code description
Multisystem inflammatory syndrome associated with COVID-19, unspecified

Primary outcomes

1

Description
Symptoms of the infection in the lower respiratory tract
Timepoint
Before and after hospitalization
Method of measurement
Procalcitonin test, chest x-ray

Secondary outcomes

1

Description
Duration of hospitalization
Timepoint
After discharge
Method of measurement
Determining hospitalization days using patient record

2

Description
Re-hospitalization
Timepoint
After discharge
Method of measurement
Number of readmission times

Intervention groups

1

Description

Intervention group: In addition to applying the routine approaches of the inpatient ward, 5 cc of Echinasea syrup, which is a herbal medicine made by Kimia Daroo factory affiliated to Astan Quds Razavi, will be used three times a day for 3 days in the hospital.

Category

Treatment - Drugs

2

Description

Control group: this group receives treatment and care based on routine ward protocols.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza hospital

Full name of responsible person

Seyed-Mousa Mahdizadeh

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Imam Reza Research and Treatment Center, No 7, Ibne-Sina St.

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Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Majid Ghayour Mobarhan

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Seyed-Mousa Mahdizadeh

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be 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
Not applicable
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
Undecided - It is not yet known if there will be a plan to make this available