

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 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 sciences

Country

Iran (Islamic Republic of)

Phone

+98 51 3859 1511

Email address

mahdizadehm@mums.ac.ir

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		NO 2, Daneshgah St, Mashhad University of Medical Sciences.	
Public title	Evaluation of the effect of Echinacea syrup on outcome in lower of respiratory infections of COVID-19	City	Mashhad
Purpose	Treatment	Province	Razavi Khorasan
Inclusion/Exclusion criteria		Postal code	13944-91388
Inclusion criteria:	Definitive diagnosis of Covid 19 Willingness to participate Evidence of symptoms of lower respiratory infections	Approval date	2022-04-09, 1401/01/20
Exclusion criteria:	Having underlying diseases such as COPD deformity in the chest	Ethics committee reference number	IR.MUMS.REC.1401.013
Age	No age limit	Health conditions studied	
Gender	Both	1	
Phase	3	Description of health condition studied	Covid-19
Groups that have been masked	Data analyser	ICD-10 code	U10.9
Sample size	Target sample size: 66	ICD-10 code description	Multisystem inflammatory syndrome associated with COVID-19, unspecified
Randomization (investigator's opinion)	Randomized	Primary outcomes	
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.	1	
Blinding (investigator's opinion)	Single blinded	Description	Symptoms of the infection in the lower respiratory tract
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).	Timepoint	Before and after hospitalization
Placebo	Not used	Method of measurement	Procalcitonin test, chest x-ray
Assignment	Parallel	Secondary outcomes	
Other design features		1	
Secondary Ids	empty	Description	Duration of hospitalization
Ethics committees		Timepoint	After discharge
1		Method of measurement	Determining hospitalization days using patient record
Ethics committee		2	
Name of ethics committee	Ethics committee of Mashhad University of Medical Sciences Ethics	Description	Re-hospitalization
Street address		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

Street address

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

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mahdizadehm@mums.ac.ir

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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Mahshhad University of Medical Sciences, Daneshgah St.

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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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Person responsible for updating data

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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