

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Aug 2026

Evaluation of the effectiveness of gabapentin and montelukast + gabapentin combination compared to dextromethorphan in the improvement of cough in patients with COVID-19 pneumonia

Protocol summary

Study aim

comparison of improving cough in patients with covid-19 between gabapentin, gabapentin+montelukast, and dextromethorphan groups

Design

Open-label randomized controlled clinical trial

Settings and conduct

The research will take place at Isfahan University of Medical Sciences' Al-Zahra Hospital. The medicine described in the previous section will be prescribed to participants. Patients in all three groups will receive standard care based on the doctor's recommendations and prescriptions (infectious disease specialist). Questionnaires will be filled out before the study begins, during the treatment, and at the conclusion.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1- Covid-19 infection with any severity with the criteria of pulmonary involvement in CT scan of the lung with RT PCR test 2- no intubation 3- Age older than or equal to 18 years 4- BCSS score higher than 2
Exclusion criteria: 1- Intubation (mechanical ventilation), 2- Sensitivity to drugs, 3- Decreased level of consciousness, 4- Intolerance of PO, 5- discharge earlier than 6 days, 6- Chronic and allergic lung disease, 7- Consumption of ACE inhibitors 8- Consumption of SSRIs / SNRIs by patients

Intervention groups

In this study, there will be two intervention groups and a control group, which are described below: Intervention group 1: Gabapentin 300 mg capsule every 8 hours will be prescribed for at least 6 days Intervention group 2: Gabapentin 300 mg capsules plus Montglucast 10 mg tablets daily will be prescribed for at least 6 days. Control group: Dextromethorphan 30 cc syrup will be prescribed every 8 hours for at least 6 days.

Main outcome variables

cough severity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150721023282N24**

Registration date: **2022-12-21, 1401/09/30**

Registration timing: **registered_while_recruiting**

Last update: **2022-12-21, 1401/09/30**

Update count: **0**

Registration date

2022-12-21, 1401/09/30

Registrant information

Name

Rasool Soltani

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 3792 7067

Email address

soltani@pharm.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-06-22, 1401/04/01

Expected recruitment end date

2023-06-21, 1402/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty	Isfahan University of Medical Sciences
Scientific title	Street address
Evaluation of the effectiveness of gabapentin and montelukast + gabapentin combination compared to dextromethorphan in the improvement of cough in patients with COVID-19 pneumonia	Hezar-Jerib Ave.
	City
	Isfahan
	Province
	Isfahan
	Postal code
	8174673461
Public title	Approval date
The effect of gabapentin and the combination of gabapentin and montelukast on cough in Covid-19 patients	2021-01-16, 1399/10/27
Purpose	Ethics committee reference number
Supportive	IR.MUI.RESEARCH.REC.1399.952
Inclusion/Exclusion criteria	Health conditions studied
Inclusion criteria:	<u>1</u>
Age over 18 years Infection of Covid-19 with any severity with the criteria of pulmonary involvement in lung CT scan with positive test RT PCR Covid-19 BCSS score higher than 2 Oral intake (PO) tolerance	Description of health condition studied
Exclusion criteria:	COVID-19
mechanical ventilation Allergy to drugs Loss of consciousness discharge earlier than 6 days Chronic underlying and allergic lung disease	ICD-10 code
	U07.1
	ICD-10 code description
	COVID-19
Age	Primary outcomes
From 18 years old	<u>1</u>
Gender	Description
Both	Cough severity
	Timepoint
	Before and after the intervention
Phase	Method of measurement
3	VAS (Visual analog scale)
Groups that have been masked	Secondary outcomes
<i>No information</i>	empty
Sample size	Intervention groups
Target sample size: 185	<u>1</u>
Randomization (investigator's opinion)	Description
Randomized	Intervention group: gabapentin 300-mg Capsules , every 8 hours, for 6 days
Randomization description	Category
At the arrival of each patient, using a random number table, a random number will be selected for him/her by putting the finger on the table with closed eyes. If even, odd or zero numbers are selected, the patient is entered into dextromethorphan, gabapentin and gabapentin/monteloukast groups, respectively.	Treatment - Drugs
Blinding (investigator's opinion)	<u>2</u>
Not blinded	Description
Blinding description	Intervention group: gabapentin 300-mg Capsules+ montelukast 10-mg, every 8 hours, for 6 days
Placebo	Category
Not used	Treatment - Drugs
Assignment	<u>3</u>
Parallel	Description
Other design features	Control group: dextromethorphan 30-mg cyrup, every 8
Secondary Ids	
empty	
Ethics committees	
<u>1</u>	
Ethics committee	
Name of ethics committee	

hours, for 6 days
Category
Treatment - Drugs

Country of origin
Type of organization providing the funding
Academic

Recruitment centers

1

Recruitment center

Name of recruitment center
Al-Zahra hospital
Full name of responsible person
Rasool Soltani
Street address
Soffeh
City
Isfahan
Province
Isfahan
Postal code
8174675731
Phone
+98 31 3620 2020
Email
alzahra@mui.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Dr Mansour Siavash Dastjerdi
Street address
Hezar jarib
City
Isfahan
Province
Isfahan
Postal code
81746-73461
Phone
+98 31 3668 7898
Email
research@mui.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Esfahan 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

Person responsible for general inquiries

Contact

Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Rasool Soltani
Position
Associate Professor
Latest degree
Specialist
Other areas of specialty/work
Medical Pharmacy
Street address
Hezar-Jerib Ave.
City
Isfahan
Province
Isfahan
Postal code
8176776161
Phone
+98 31 3786 5537
Email
soltani@pharm.mui.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Rasool Soltani
Position
Professor
Latest degree
Specialist
Other areas of specialty/work
Medical Pharmacy
Street address
Hezar-Jerib Ave.
City
Isfahan
Province
Isfahan
Postal code
8176776161
Phone
+98 31 3786 5537
Email
soltani@pharm.mui.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person

Rasool Soltani

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Medical Pharmacy

Street address

Hezar-Jerib Ave

City

Isfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3792 7067

Email

soltani@pharm.mui.ac.ir

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Confidentiality of patients data

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available