Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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

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

Public title
The effect of gabapentin and the combination of gabapentin and montelukast on cough in Covid-19 patients

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
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

Exclusion criteria:
mechanical ventilation Allergy to drugs Loss of consciousness discharge earlier than 6 days Chronic underlying and allergic lung disease

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **185**

Randomization (investigator's opinion)
Randomized

Randomization description
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.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Isfahan University of Medical Sciences

Street address
Hezar-Jerib Ave.

City
Isfahan

Province
Isfehan

Postal code
8174673461

Approval date
2021-01-16, 1399/10/27

Ethics committee reference number
IR.MUI.RESEARCH.REC.1399.952

Health conditions studied

1

Description of health condition studied
COVID-19

ICD-10 code
U07.1

ICD-10 code description
COVID-19

Primary outcomes

1

Description
Cough severity

Timepoint
Before and after the intervention

Method of measurement
VAS (Visual analog scale)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: gabapentin 300-mg Capsules , every 8 hours, for 6 days

Category
Treatment - Drugs

2

Description
Intervention group: gabapentin 300-mg Capsules+ montelukast 10-mg, every 8 hours, for 6 days

Category
Treatment - Drugs

3

Description
Control group: dextromethorphan 30-mg cyrup, every 8

hours, for 6 days

Category

Treatment - Drugs

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

Isfehan

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

Isfehan

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

Country of origin

Type of organization providing the funding

Academic

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

Isfehan

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

Isfehan

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
Isfehan
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