

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

05 Jun 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

Isfahan

#### 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  
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8174675731  
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+98 31 3620 2020  
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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  
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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  
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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Esfahan University of Medical Sciences  
**Full name of responsible person**  
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**Position**  
Professor  
**Latest degree**  
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**Other areas of specialty/work**  
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## 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

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**Phone**

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**Email**

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**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