

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 May 2026

### Evaluation of the Efficacy and safety of dolutegravir in patients with moderate COVID-19 disease (randomized double blind placebo controlled trial)

#### Protocol summary

##### Study aim

The aim of this study was to evaluate the effectiveness of Dolutegravir diet and compare it with the standard diet used.

##### Design

This study is a randomized, double-blind, placebo-controlled clinical trial. In order to eliminate Confounding by indication and Confounding by severity, patient and therapists will be blind to the type of treatment.

##### Settings and conduct

Patients are divided into two groups of 50. In one group, the drug will be given at a dose of 50 mg for 7 days and the placebo will be administered with standard treatments in the other group. Patients and care provider are blinded.

##### Participants/Inclusion and exclusion criteria

Inclusion: Aged between 18 to 80, Definitive diagnosis of covid-19,  $\leq 8$  days since illness onset, Having fever ( $\geq 37.8$  ° C at any time), dry cough, shortness of breath or fatigue Involvement of 3 or more lobes of the pulmonary lobes or  $>O_2Sat < 94\%$  , Written consent of patients  
Exclusion: Severe hepatic impairment, Patients taking Phenytoin, Fosphenytoin, Oxcarbazepine, Phenobarbital, Primidone and St John's Wort, History of disease because of COVID-19, History of taking Covid-19 experimental drug, lactation, Requires intubation at admission, Sensitivity to Dolutegravir, Severe disability and Patient dissatisfaction with the study

##### Intervention groups

Receive dolutegravir at a dose of 50 mg daily for 7 days + standard treatment regimen in the intervention group  
Receive placebo daily for 7 days + standard treatment regimen in the control group

##### Main outcome variables

Clinical recovery after 14 days from the start of treatment, No need for intensive care and mechanical ventilation, Decrease the hospital admission time,

Decrease the time to need nasal oxygen , Eradication of the virus from the nose and throat in RT-PCR test

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200328046886N3**

Registration date: **2021-07-18, 1400/04/27**

Registration timing: **prospective**

Last update: **2021-07-18, 1400/04/27**

Update count: **0**

##### Registration date

2021-07-18, 1400/04/27

##### Registrant information

##### Name

Hamideh Abbaspour

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 11 4203 1035

##### Email address

dr.abbaspour1@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-08-22, 1400/05/31

##### Expected recruitment end date

2021-10-23, 1400/08/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**  
2021-11-21, 1400/08/30

**Scientific title**  
Evaluation of the Efficacy and safety of dolutegravir in patients with moderate COVID-19 disease (randomized double blind placebo controlled trial)

**Public title**  
Evaluation of the Efficacy and safety of dolutegravir in patients with moderate COVID-19 disease

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
1) Aged between 18 to 80 2) Patients with definitive diagnosis of covid-19 (Lung involvement in Covid-19 compliant CT confirmed by coronavirus pneumonia). 3)  $\leq 8$  days since illness onset 4) Having one of the following symptoms: Fever ( $\geq 37.8$  ° C at any time), Dry cough, Shortness of breath, Fatigue 5) One of the following: Involvement of 3 or more lobes of the pulmonary lobes,  $>O_2Sat < 94\%$  6) Patients with signing Informed Consent Form Willing  
**Exclusion criteria:**  
1) Severe hepatic impairment (Child-pough C) 2) Patients taking Phenytoin, Fosphenytoin, Oxcarbazepine, Phenobarbital, Primidone and St John's Wort 3) History of disease because of COVID-19 4) History of taking Covid-19 experimental drug 5) lactation 6) Requires intubation at admission 7) Sensitivity to Dolutegravir 8) Severe disability that prevents cooperation 9) Patient dissatisfaction with the study

**Age**  
From **18 years** old to **80 years** old

**Gender**  
Both

**Phase**  
3

**Groups that have been masked**

- Participant
- Care provider

**Sample size**  
Target sample size: **100**  
Actual sample size reached: **100**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
This study is a parallel randomized double-blind clinical trial. To randomize the treatment assignment to the two treatment arms A and B (standard protocol regimen and recommended regimen, respectively) from Restricted randomization schemes by Blocking method and online software Sealed envelope (<https://www.sealedenvelope.com/simple-randomiser/v1/lists>) was used and thus 100 patients will be placed in 25 blocks of 4.

**Blinding (investigator's opinion)**  
Double blinded

**Blinding description**

It should be noted that in order to eliminate Confounding by indication as well as Confounding by severity, therapist clinicians and patients will be blind (Double masking) regarding the type of treatment (Treatment assignment). Assignment of treatment in accordance with the above blocking will be done under the supervision of a clinical pharmacist and by sending Sealed envelope. On the other hand, the final evaluator and analyst of the study are aware of how the treatment is allocated.

**Placebo**  
Used

**Assignment**  
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Research Ethics Committee of Mazandaran University of Medical Sciences

##### Street address

Imam Square, Joybar Three Ways, the beginning of Valiasr Highway, the headquarters of Mazandaran University of Medical Sciences

##### City

Sari

##### Province

Mazandaran

##### Postal code

۴۸۱۵۷۳۳۹۷۱

#### Approval date

2021-02-24, 1399/12/06

#### Ethics committee reference number

IR.MAZUMS.REC.1399.972

## Health conditions studied

### 1

#### Description of health condition studied

COVID-19

#### ICD-10 code

U07.1

#### ICD-10 code description

COVID-19, virus identified

## Primary outcomes

### 1

#### Description

Recovery after 10 days from the start of the study is defined as follows:  $O_2sat \geq 95\%$  or improvement compared to baseline no fever, no dyspnea, no cough or

improved cough, No fatigue or improved fatigue, oral intake for at least 24 hours

**Timepoint**

Daily in all duration of study

**Method of measurement**

By designed investigator checklist

## Secondary outcomes

### 1

**Description**

Recovery within 14 days after starting medication

**Timepoint**

daily until the day 14 after beginning of intervention

**Method of measurement**

By a designed checklist

### 2

**Description**

Survival rate

**Timepoint**

Daily

**Method of measurement**

By a designed checklist

### 3

**Description**

Number of days hospitalized

**Timepoint**

Daily

**Method of measurement**

By a designed checklist

### 4

**Description**

Number of days intubated

**Timepoint**

Daily

**Method of measurement**

By a designed checklist

## Intervention groups

### 1

**Description**

In the intervention group, patients receive duloxetine 50 mg daily for 7 days in addition to the standard treatment regimen. This study was performed on patients with definitive diagnosis of Covid-19 by CT scan at Razi Hospital in Ghaemshahr and evaluated the efficacy and safety of Duloxetine. It should be noted that in order to eliminate Confounding by indication as well as Confounding by severity, in addition to patients, therapists and the treating physician will be blind to the type of treatment.

**Category**

Treatment - Drugs

### 2

**Description**

In the control group, patients receive placebo for 7 days along with the standard treatment regimen.

**Category**

Treatment - Drugs

## Recruitment centers

### 1

**Recruitment center****Name of recruitment center**

Razi hospital

**Full name of responsible person**

Hamideh Abbaspour kasgari

**Street address**

Razi educational center, Yousefreza Ave, مازندران-قائم شهر-خیابان یوسف رضا-مرکز آموزشی درمانی رازی

**City**

Qaemshahr

**Province**

Mazandaran

**Postal code**

4565686143

**Phone**

+98 11 4221 8018

**Fax**

+98 11 4221 8011

**Email**

razi-ghh@mazums.ac.ir

**Web page address**

<https://razihospital.mazums.ac.ir/>

## Sponsors / Funding sources

### 1

**Sponsor****Name of organization / entity**

Mazandaran University of Medical Sciences

**Full name of responsible person**

Dr. Majid Saeedi

**Street address**

Imam Square, Joybar Three Ways, the beginning of Valiasr Highway, the headquarters of Mazandaran University of Medical Sciences

**City**

Sari

**Province**

Mazandaran

**Postal code**

4815733971

**Phone**

+98 11 3304 4000

**Email**

publicrel@mazums.ac.ir

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor**

**organization/entity?**

Yes

**Title of funding source**

Mazandaran 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**

Mazandaran University of Medical Sciences

**Full name of responsible person**

Hamideh Abbaspour Kasgari

**Position**

Associate professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Medical Pharmacy

**Street address**

Faculty of pharmacy, Payambar Azam academic complex, 18 km of Khazar Abad Ave, Sari

**City**

Sari

**Province**

Mazandaran

**Postal code**

4763947444

**Phone**

+98 11 4203 1035

**Email**

dr.abbaspour1@yahoo.com

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Mazandaran University of Medical Sciences

**Full name of responsible person**

Hamideh Abbaspour Kasgari

**Position**

Associate professor

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Mazandaran University of Medical Sciences

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**Email**

dr.abbaspour1@yahoo.com

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

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

all collected deidentified IPD

**When the data will become available and for how long**

after complete of the study

**To whom data/document is available**

data only available for people working in academic institutions

**Under which criteria data/document could be used**

any change of the data avoided

**From where data/document is obtainable**

the preferred way of communication is email address

**What processes are involved for a request to access**

**data/document**

in few time after send email the data could be available

**Comments**