

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 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, ≤ 8 days since illness onset, Having fever ($\geq 37.8^{\circ}\text{C}$ at any time), dry cough, shortness of breath or fatigue Involvement of 3 or more lobes of the pulmonary lobes or $\text{SpO}_2 < 94\%$, 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) ≤ 8 days since illness onset 4) Having one of the following symptoms: Fever ($\geq 37.8^{\circ}\text{C}$ at any time), Dry cough, Shortness of breath, Fatigue 5) One of the following: Involvement of 3 or more lobes of the pulmonary lobes, $\text{O}_2\text{Sat} < 94\%$ 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: $\text{O}_2\text{sat} \geq 95\%$ 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 dulotegravir 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 Dulotegravir. 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,
Qhaemshahr, Mazandaran
مازندران-قائم‌شهر-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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Person responsible for updating data**Contact****Name of organization / entity**

Mazandaran University of Medical Sciences

Full name of responsible person

Hamideh Abbaspour Kasgari

Position

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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