Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 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 Dolatgravir 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 (≥ 37.8 ° C at any time), dry cough, shortness of breath or fatigue Involvement of 3 or more lobes of the pulmonary lobes or >O2Sat< 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 dulotegravir 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 (≥ 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, >O2Sat< 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: O2sat ≥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 اموزشی درمانی رازی

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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

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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
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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