

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Investigating the effectiveness of the use of hesperidin on the clinical conditions of patients with the new coronavirus (SARS-COV-2)

Protocol summary

Study aim

Investigation of the effect of hesperidin use in patients with new coronavirus (COVID-19)

Design

A clinical trial with a control group, with parallel, two-way blind and randomized groups on 60 patients

Settings and conduct

The present study will be a randomized clinical trial and the test population will be among the patients with new coronavirus referred to Dr. Masih Daneshvari Hospital in Tehran. All patients with admission criteria will enter the study after providing complete explanations and obtaining written consent and will enter the groups using the table of random numbers.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Patients with coronavirus are admitted to the new intensive care unit. Exclusion criteria: patients with intubation conditions, history of severe liver and kidney disease, patient dissatisfaction with participation in the project, age over 65 and under 18 years, history of corticosteroid therapy

Intervention groups

In group therapy, patients receive 1 mg of hesperidin orally every 6 hours for 5 days. In the control group, patients will be under normal supervision without prescribing hesperidin. The variables are then measured over a period of time.

Main outcome variables

C-Reactive Proteine: Alanine aminotransferase: Aspartate aminotransferase: Bilirubine: lactate dehydrogenase: Creatinine: White blood cells

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150725023332N5**

Registration date: **2021-04-06, 1400/01/17**

Registration timing: **retrospective**

Last update: **2021-04-06, 1400/01/17**

Update count: **0**

Registration date

2021-04-06, 1400/01/17

Registrant information

Name

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2283 1058

Email address

alirezajahangiri@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-06-21, 1399/04/01

Expected recruitment end date

2020-09-22, 1399/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effectiveness of the use of hesperidin on the clinical conditions of patients with the new coronavirus (SARS-COV-2)

Public title

The effect of hesperidin use on the clinical condition of patients with the new coronavirus

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with new coronavirus who hospitalized in the intensive care unit

Exclusion criteria:

Patients with intubation conditions History of severe liver disease History of severe renal disease Patient dissatisfaction to participate in the project Age over 65 and under 18 years

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

With simple randomization and using a random number table and individual randomization unit. To randomize, we use a table consisting of random digits 0 to 9. Each digit of this table is repeated the same on average. There is no pattern of recognizable numbers. In this method, each number is assigned to a treatment group. We start from the first line of the table and move down line by line. For the two treatments, we put the numbers 0 to 4 for treatment A and the numbers 5 to 9 for treatment B. The numbers in the first line of the table are as follows: 0,5,2,7,8,4,3,7,4,1,6,8,3,8,5,1,5,6,9,6, ... Now for people based on the above numbers, we have the following allocation: A, B, A, B, B,... We will continue the above process until the two groups are completed.

Blinding (investigator's opinion)

Single blinded

Blinding description

To prevent any possible complications, the primary caregiver is aware of the allocation of treatment groups. Patients in the study were also not blinded to the treatment they were receiving. Researchers responsible for data collection and analysis are not aware of the allocation of different study groups.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee in Biomedical Research, Shahid Beheshti University

Street address

Next to Ayatollah Taleghani Hospital ,Evin , Tehran, Iran

City

Tehran

Province

Tehran

Postal code

198396-3113

Approval date

2020-05-26, 1399/03/06

Ethics committee reference number

IR.SBMU.NRITLD.REC.1399.126

Health conditions studied

1

Description of health condition studied

Covid-19

ICD-10 code

U07.02

ICD-10 code description

COVID-19, virus not identified

Primary outcomes

1

Description

lactate dehydrogenase

Timepoint

Before prescribing of Hesperidin and 5 days after taking it

Method of measurement

Lactate dehydrogenase testing by blood sampling

2

Description

Cratinin

Timepoint

Before prescribing of Hesperidin and 5 days after taking it

Method of measurement

Testing for creatinine in the serum

3

Description

BUN

Timepoint

Before prescribing of Hesperidin and 5 days after taking it

Method of measurement

Blood urea test

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients in this group, in addition to conventional treatment, receive 1 mg of hesperidin orally every 6 hours for 5 days.

Category

Treatment - Drugs

2

Description

control group: Patients in this group receive only conventional therapies, and hesperidin will not be prescribed.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Masih Daneshvari Hospital

Full name of responsible person

Alireza Jahangirifard

Street address

The Hospital of Messiah Daneshvari, Darabad

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin zarghi

Street address

Taleghani Hospital, Shahid Beheshti University of Medical Sciences and Health Services

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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

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Alireza jahangirifard

Position

Associate Professor دانشیار

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

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Full name of responsible person

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Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

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Research Director

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable