Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Investigating the effectiveness of the use of hesperidin on the clinical con ditions 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 o n the clinical conditions of patients with the new coronavi rus (SARS-COV-2)

Public title
The effect of hesperidin use on the clinical condition of p atients 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
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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
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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 Professorدانشیار
Latest degree
Subspecialist
Other areas of specialty/work
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Person responsible for updating data

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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