Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Evaluation of the effect of Afsantin in the treatment of COVID 19 patients

Protocol summary

Study aim
Evaluation of the effect of Afsantin in the treatment of COVID 19 patients
Design
This clinical trial was performed on 80 patients, divided into two groups of 40, including a control group and parallel groups. This study is Double-blind and block randomization method is used.
Settings and conduct
The field of work is clinical - internal. This study is performed in the Tohid Hospital in Sanandaj. Patients, physicians, and nurses who evaluate the outcomes will be blind to the groups studied.
Participants/Inclusion and exclusion criteria
Inclusion Criteria: Confirmed diagnosis of COVID19 with RT-PCR, Hospitalized patients, Ventilator independent patients Exclusion Criteria: Pregnancy, Breastfeeding, Diabetes, Severe renal failure, Metabolic acidosis, Severe respiratory failure, Taking anticoagulants
Intervention groups
Patients in both groups receive the treatment based on the Covid-19 National Guidelines. Patients in the intervention group, in addition to the standard treatment protocol, receive Afsantin Capsule in the form of 1000 mg capsules four times a day for 14 days and the control group also receives placebo according to the above method.
Main outcome variables
Fever, Cough, Muscle pain, Blood oxygen saturation percentage, CRP, CBC, Respiratory Rate, Heart Rate

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20190415043279N6**
Registration date: **2020-07-24, 1399/05/03**
Registration timing: **registered_while_recruiting**
Last update: **2020-07-24, 1399/05/03**
Update count: **0**
Registration date
2020-07-24, 1399/05/03

Registrant information
Name
Pezhman Sharifi
Name of organization / entity
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2020-07-10, 1399/04/20
Expected recruitment end date
2020-10-11, 1399/07/20
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of the effect of Afsantin in the treatment of COVID 19 patients

Public title
Evaluation of the effect of Afsantin on COVID 19
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Definitive confirmation of Covid 19 based on RT-PCR results Hospitalized patients Ventilator independent

patients

Exclusion criteria:

Pregnancy Breastfeeding Diabetes Severe renal failure Metabolic acidosis Severe respiratory failure Taking anticoagulants

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Using block randomization method with a block size of 4. Sampling method at this study will be according to random allocation. Participants will enter the study according to inclusion criteria, and then will be divided into two groups according to randomization table. One group will receive Afsantin Capsule and the other will receive placebo. The participants and administrator do not have any information about content of capsules (double blinded study). The list of randomization was computer-generated. supplements and placebo capsules were placed in completely identical packages and were coded by someone who was unaware of the nature of the study in numbered bottles based on the list. And another person who was unaware of the contents of the pack provided them to the patients.

Blinding (investigator's opinion)

Double blinded

Blinding description

All supplements and placebo capsules were identical with respect to appearance and only differed in coding of the capsules. The treatment code of the intervention supplements was blinded for subjects, investigators and staff involved in the conduct of the study.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kurdistan University of Medical Sciences

Street address

Vice Chancellor for research of Kurdistan University of Medical Sciences, Pasdaran Blvd, Sanandaj, Iran

City

Sanandaj

Province

Kurdistan

Postal code

66177-13446

Approval date

2020-07-05, 1399/04/15

Ethics committee reference number

IR.MUK.REC.1399.048

Health conditions studied

1

Description of health condition studied

Covid-19

ICD-10 code

U07.1

ICD-10 code description

Other coronavirus as the cause of diseases classified elsewhere

Primary outcomes

1

Description

Fever

Timepoint

At the beginning of the study (before the intervention) and after the intervention

Method of measurement

Thermometer

2

Description

Cough

Timepoint

At the beginning of the study (before the intervention) and after the intervention

Method of measurement

Questionnaire

3

Description

Muscle pain

Timepoint

At the beginning of the study (before the intervention) and after the intervention

Method of measurement

Questionnaire

4

Description
C Reactive Protein (CRP)
Timepoint
At the beginning of the study (before the intervention) and after the intervention
Method of measurement
Agglutination

5

Description
Blood oxygen saturation percentage
Timepoint
At the beginning of the study (before the intervention) and after the intervention
Method of measurement
Pulse oximeter

6

Description
CBC
Timepoint
At the beginning of the study (before the intervention) and after the intervention
Method of measurement
Cell Counter

7

Description
Respiratory Rate
Timepoint
At the beginning of the study (before the intervention) and after the intervention
Method of measurement
By observing the occurrence of breaths

8

Description
Heart Rate
Timepoint
At the beginning of the study (before the intervention) and after the intervention
Method of measurement
Pulse oximeter

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The Afsantin capsule is taken as a 1000 mg soft capsule four times a day for 14 days.
Category
Placebo

2

Description
Control group: The placebo is taken as a capsule four times a day for 14 days.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Tohid Hospital
Full name of responsible person
Noshad Mohammadi
Street address
Tohid Hospital, Geriashan Ave
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Sanandaj University of Medical Sciences
Full name of responsible person
Dr. Afshin Maleki
Street address
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maleki43@yahoo.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Sanandaj 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

Sanandaj University of Medical Sciences

Full name of responsible person

Noshad Mohammadi

Position

Internal resident

Latest degree

Medical doctor

Other areas of specialty/work

Internal Medicine

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Pulmonology

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Person responsible for updating data

Contact

Name of organization / entity

Sanandaj University of Medical Sciences

Full name of responsible person

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Position

مربی

Latest degree

Master

Other areas of specialty/work

Microbiology

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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

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

Statistical Analysis Plan

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

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