

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Dec 2023

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

Country

Iran (Islamic Republic of)

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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

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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
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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