Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Investigation of the effect of artemisinin Capsules and Dermaneh (Artemisia persica)and Afsantin)Artemisia absinthium(Capsules in the treatment of coronavirus COVID-19 virus in Afzalipour hospital,kerman, 2020

Protocol summary

Study aim
Investigation of the effect of artemisinin Capsules, Dermaneh (Artemisia persica) Capsules and Afsantin (Artemisia absinthium) Capsules on the treatment of patients with corona (COVID-19)

Design
A randomized, controlled, three-blind, placebo-controlled clinical trial, triple-blind, randomized, phase 2 on 30 patients. The table of random numbers is used for randomization.

Settings and conduct
Afzalipour hospital, Kerman, 2020, Care provider, Investigator, outcome assessor and data analyzer are blind. The drugs were the same in color and same shape. Care provider, Investigator, outcome assessor and data analyzer are blind did not know anything about the drug.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Signing consent form; Age 18-65 years old; PCR positive test or characteristic signs on a CT scan of the chest with mild to moderate clinical manifestations according to the National Early Warning Score (NEWS) Exclusion criteria: Severe liver disease; Severe renal disease; allergic reaction to used drugs in study; Pregnant or breastfeeding women; transfer to the intensive care unit.

Intervention groups
The intervention group will receive 100 mg artemisinin, two Dermaneh capsules and two Afsantin capsules the control group will receive placebo capsules daily. Patients will be given daily capsules in packs containing 70capsules and we ask patients to take five capsules daily for 14 days.

Main outcome variables
Lymphocytes,C-reactive protein, Respiratory Rate, Oxygen saturation, Headache, Muscle pain, Sore throat, Anorexia, Fatigue and Cough

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20201027049164N6**
Registration date: **2022-03-29, 1401/01/09**
Registration timing: **retrospective**

Last update: **2022-03-29, 1401/01/09**
Update count: **0**

Registration date
2022-03-29, 1401/01/09

Registrant information
Name
Masumeh Ghazanfarpour
Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2020-11-10, 1399/08/20
Expected recruitment end date
2021-02-18, 1399/11/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date

empty

Scientific title
Investigation of the effect of artemisinin Capsules and Dermaneh (Artemisia persica)and Afsantin)Artemisia absinthium(Capsules in the treatment of coronavirus COVID-19 virus in Afzalipour hospital,kerman, 2020

Public title
Investigation of the effect of artemisinin and Dermaneh and Afsantinin the treatment of coronavirus COVID-19 virus

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients with signing Informed Consent Age 18-65 years old Positive CRP test for SARS-CoV-2 virus or characteristic signs on a CT scan of the chest with mild to moderate clinical manifestations according to the National Early Warning Score (NEWS) (mild: 1-4 / moderate: 5-6)

Exclusion criteria:
Receipt of any another experimental treatment Severe liver disease Known allergic reaction to drugs Severe renal disease Pregnant or breastfeeding women transfer to the intensive care unit

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

Gender
Both

Phase
3

Groups that have been masked

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

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Randomized

Randomization description
For randomization, the table of random numbers will be used. First, a code from 01 to 30, was given to patient. The first 15 was used for intervention group whereas the other15 for the control. We placed a finger on the columns of the random numbers table to determine start point, and the last two digits of each column were considered. It was ignored if numbers were higher For example, 23 code received placebo.

Blinding (investigator's opinion)
Double blinded

Blinding description
Researchers, nurses, and patients will be not aware of medication or placebo because they will be similar in appearance

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Kerman University of Medical Sciences

Street address
Deputy of Research and Technology;ebne-e-Sina St.,Jahad Blvd., Kerman,Iran

City
Kerman

Province
Kerman

Postal code
7619813159

Approval date
2020-10-24, 1399/08/03

Ethics committee reference number
IR.KMU.REC.1399.292

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
Oxygen saturation

Timepoint
At the beginning (before the intervention) and 14 days after intervention

Method of measurement
Pulse Oximeter

2

Description
Respiratory Rate

Timepoint
At the beginning of the study (before the intervention) and14 days after intervention

Method of measurement
Respiratory Count

3

Description
C-reactive protein
Timepoint
At the beginning of the study (before the intervention) , 7 days after the intervention, 14 days after intervention
Method of measurement
Venous blood test

4

Description
Lymphocytes
Timepoint
At the beginning of the study (before the intervention) and 14 days after intervention
Method of measurement
Venous blood test

Secondary outcomes

1

Description
Headache
Timepoint
At the beginning of the study (before the intervention) and 14 days after the intervention
Method of measurement
Questionnaire

2

Description
Muscle pain
Timepoint
At the beginning of the study (before the intervention) and 14 days after the intervention
Method of measurement
Questionnaire

3

Description
Sore throat
Timepoint
At the beginning of the study (before the intervention) and 14 days after the intervention
Method of measurement
Questionnaire

4

Description
Anorexia
Timepoint
At the beginning of the study (before the intervention) and 14 days after the intervention
Method of measurement
Questionnaire

5

Description
Fatigue
Timepoint
At the beginning of the study (before the intervention)and 14 days after the intervention
Method of measurement
Questionnaire

6

Description
Cough
Timepoint
At the beginning of the study (before the intervention) and 14 days after the intervention
Method of measurement
Questionnaire

Intervention groups

1

Description
Intervention group: The intervention group will receive two Dermaneh capsules of artemisinin 100 mg, two capsules (each containing 5oo mg Dermaneh) and two Dermaneh capsules (each containing 500 mg Afsantin) daily. Patients will be given daily capsules in packs containing 70capsules and we ask patients to take five capsules daily for 14 days.
Category
Treatment - Drugs

2

Description
Control group: The control group will receive placebo capsules daily. Patients will be given capsules in packs containing 84 capsules and we ask patients to take six capsules daily for 14 days.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Afzalipour hospital
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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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
Vice Chancellor for Research and Technology of Kerman 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
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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

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

Analytic Code

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

Data Dictionary

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