Clinical Trial Protocol
Iranian Registry of Clinical Trials

25 Oct 2020

Comparison Efficacy of extract plants of Zingiber , cinnamon , zataria multiflora with standard protocol in treatment and clinical improvement of patients with moderate to severe symptoms of covid-19

Protocol summary

Study aim

Comparison Efficacy of extract plants of Zingiber, Cinnamon zeylanicum, Zataria multiflora with standard treatment in adult patients with moderate to severe symptoms of Covid 19

Design

In this blinded randomized parallel clinical trial, 80 Patients are allocated randomly with simple sequential allocation in one of the two groups (herbal extract or standard protocol) and receive the intervention of that group.

Settings and conduct

Adult patients with Covid 19 are randomly assigned to one of the two groups and receive appropriate intervention in the control group according to the national protocol. In the second group, in addition to the standard daily intervention, a capsule of a combined extract of 3 plants is consumed for one week every morning after a meal with a glass of water. Days 3, 0, 5, 7, 10 and 14 of the patients in terms of temperature, presence and severity of cough, dyspnea, number of breaths, oxygen saturation of the blood (pulse oximetry), blood pressure and general condition Check . Basic serum samples and LFT and IL4 and 6 and imaging based on the standard protocol are at the beginning and on days 7, and if a specific complication develops extract discontinued and standard treatment will be done.

Participants/Inclusion and exclusion criteria

Inclusion criteria:Adult patients (18-75 year) suffering from nCovid-19 with moderate to severe symptoms having informed consent form Exclusion criteria:Poor condition patients,inability to take oral drugs, and those with a history of herbal or medicinal allergy.

Intervention groups

According to the National Protocol,patients with Covid-19 in addition to the standard treatment n daily consumed one capsule of 3 plant extracts for one week every morning after a meal with a glass of water.

Main outcome variables

Cough severity,dyspnea,temperature,respiratory rate,oxygen saturation blood pressure and change in imaging

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20081011001323N25**
Registration date: **2020-05-17, 1399/02/28**
Registration timing: **prospective**

Last update: **2020-05-17, 1399/02/28**
Update count: **0**

Registration date

2020-05-17, 1399/02/28

Registrant information

Name

Sadrollah Mehrabi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

recruiting

Funding source

Expected recruitment start date

2020-05-21, 1399/03/01

Expected recruitment end date

2020-12-20, 1399/09/30

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison Efficacy of extract plants of Zingiber , cinnamon , zataria multiflora with standard protocol in treatment and clinical improvement of patients with moderate to severe symptoms of covid-19

Public title
Efficacy of extract of of Zingiber cinnamomum and zataria multiflora in covid-19 disease
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age over 18 years suffering from CAovid-19 with moderate to severe symptoms Having informed consent for entrance of study
Exclusion criteria:
Developing any complication during study Covid-19 patients with poor condition(very ill or intubated) Inability to use oral drugs Presence of any concomitant cardiac,hepatic or renal disease Having any allergy to chemical or herbal drugs Lack of desire to continue studying
Age
From **18 years** old
Gender
Both

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **80**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients are allocated randomly with simple random allocation method by use of random number table to one of each group (combined herbal extract or standard protocol) and received the intervention of that group.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Yasuj University of Medical Sciences
Street address
Yasuj University of Medical Sciences, Mottahari srteet, Yasuj, Iran
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Kohgilouyeh-va-Boyrahmad
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7591741414
Approval date
2020-04-06, 1399/01/18
Ethics committee reference number
IR.YUMS.REC.1399.029

Health conditions studied

1

Description of health condition studied
COVID-19
ICD-10 code
U07.1
ICD-10 code description
COVID-19

Primary outcomes

1

Description
clinical symptoms (presence and severity of dry cough)
Timepoint
0--3--7- 10-14 days after starting intervention
Method of measurement
Physical examination,questionnaire

2

Description
Temperature
Timepoint
0--3--7- 10-14 days after starting intervention
Method of measurement
Thermometer

3

Description
clinical symptoms (dyspnea)
Timepoint
Daily monitoring, but the result of baseline (before the initiation of intervention), and day 3,7 10 and 14 from the initiation, is recorded.
Method of measurement

Physical examination,questionnaire

4

Description
Respiratory rate
Timepoint
Daily monitoring, but the result of baseline (before the initiation of intervention), and day 3,7 10 and 14 from the initiation, is recorded.
Method of measurement
Counting the number of breaths per minute

5

Description
Blood pressure and pulse
Timepoint
Daily monitoring, but the result of baseline (before the initiation of intervention), and day 3,7 10 and 14 from the initiation, is recorded.
Method of measurement
With sphygmomanometer and pulse control

6

Description
oxygen saturation
Timepoint
Daily monitoring, but the result of baseline (before the initiation of intervention), and day 3,7 10 and 14 from the initiation, is recorded.
Method of measurement
pulseoximeter

7

Description
inflammatory response
Timepoint
Days 0,7
Method of measurement
Check of IL6,IL4,CBC,CRP,ESR

8

Description
Imaging findings
Timepoint
on the first and 7th day of treatment
Method of measurement
by chest x ray and CTscan

Secondary outcomes

1

Description
Drug side effects
Timepoint
During treatment and one week later
Method of measurement
With observation, physical exam and report of patients

Intervention groups

1

Description
Intervention group: In this group, in addition to the standard daily intervention, a capsule of a combined extract of 3 plants of Zingiber cinnamon and zataria multiflora(200 mg dried extract of each plant) made by Armagan Salamat Zagros Yasuj Company is consumed for one week every morning after a meal with a glass of water. On days 0,3,7,10,and 14 patients check for temperature, presence and severity of cough,dyspnea,body pain, respiratory rate, blood oxygen saturation(by pulse oximetry)blood pressure ,pulse rate and general condition will be checked and recorded. Also basic serum samples, renal function tests , liver function tests and x-ray or CT Scan will be checked on days 0 and 7 in all patients.
Category
Treatment - Drugs

2

Description
Control group: Routine treatment according to the latest national guideline for the treatment of new corona-virus .On days 0,3,7,10,and 14 patients check for temperature, presence and severity of cough,dyspnea,body pain, respiratory rate, blood oxygen saturation(by pulse oximetry)blood pressure ,pulse rate and general condition will be checked and recorded. Also basic serum samples, renal function tests , liver function tests and x-ray or CT Scan will be checked on days 0 and 7 in all patients.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Jalil hospital of Yasuj
Full name of responsible person
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Sponsors / Funding sources

1

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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
Yasouj 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
Yasouj University of Medical Sciences
Full name of responsible person
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Professor, Chairman of Urology Department, Yasuj University of Medical Sciences
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
There is no further information.
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available