

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 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)

Phone

+98 74 3334 6070

Email address

dr.mehrabi@yums.ac.ir

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

City

Yasuj

Province

Kohgilouyeh-va-Boyerahmad

Postal code

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

Sadrollah Mehrabi

Street address

Shahid Gharani bullvard ,Shahid Jalil hospital

City

Yasuj

Province

Kohgilouyeh-va-Boyrahmad

Postal code

7591951176

Phone

+98 74 3322 9297

Email

sadrollahm@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yasouj University of Medical Sciences

Full name of responsible person

Ali Mousavizadeh

Street address

Deputy of research, Yasuj University of Medical Sciences,, Motahari St

City

Yasuj

Province

Kohgilouyeh-va-Boyerahmad

Postal code

7591741417

Phone

+98 74 3334 6074

Email

health.epid@gmail.com

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

Sadrollah Mehrabi

Position

Professor, Chairman of Urology Department, Yasuj University of Medical Sciences

Latest degree

Subspecialist

Other areas of specialty/work

Urology

Street address

Shahid Mofateh clinic, Montazeri street, Yasuj, Iran

City

Yasuj

Province

Kohgilouyeh-va-Boyerahmad

Postal code

7591741417

Phone

+98 74 3322 1812

Email

sadrollahm@yahoo.com

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Yasouj University of Medical Sciences

Full name of responsible person

Sadrollah Mehrabi

Position

Professor, Chairman of Urology Department, Yasuj University of Medical Sciences

Latest degree

Subspecialist

Other areas of specialty/work

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Street address

Yasuj University of Medical Sciences, Mottahari Street, Yasuj, Iran

City

Yasuj

Province

Kohgilouyeh-va-Boyerahmad

Postal code

7591741417

Phone

+98 74 3322 9297

Email

sadrollahm@yahoo.com

Person responsible for updating data

Contact**Name of organization / entity**

Yasouj University of Medical Sciences

Full name of responsible person

Sadrollah Mehrabi

Position

Professor, Chairman of Urology Department, Yasuj University of Medical Sciences

Latest degree

Subspecialist

Other areas of specialty/work

Urology

Street address

Yasuj University of Medical Sciences, Mottahari Street, Yasuj, Iran

City

Yasuj

Province

Kohgilouyeh-va-Boyerahmad

Postal code

7591741417

Phone

+98 74 3322 4721

Email

sadrollahm@yahoo.com

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