Clinical Trial Protocol
Iranian Registry of Clinical Trials

21 Mar 2023

Evaluation of the effect of herbal medicine containing Saatar, Hofarigon and Fennel on reduction of pulmonary complications of COVID-19 in patients: a clinical trial

Protocol summary

Study aim
Evaluation of the effect of herbal medicine containing Saatar, Hofarigon and Fennel on reduction of pulmonary complications of COVID-19 in patients

Design
Clinical trial with control group, with parallel groups, randomized, non-blinded

Settings and conduct
This clinical trial study will be performed in Razi hospitals of Mazandaran University of Medical Sciences. Among referred patients, 40 patients will assigned into two groups of 20. First group will revived kaletra + hydroxychloroquine + herbal medicine and the second group, kaletra + hydroxychloroquine.

Participants/Inclusion and exclusion criteria
Entry requirements: Covid 19 patients with CT scan confirmation and clinical symptoms Conditions of non-entry: Covid 19 patients have severe underlying diseases

Intervention groups
Intervention group: Kaletra 200 mg/50 mg tablet every 12 hours + hydroxychloroquine 200 mg tablets every 12 hours + herbal medicine containing sage, hofariqun and fennel (5 ml 3 times a day) Control group: Kaletra 200 mg/50 mg tablet every 12 hours + hydroxychloroquine 200 mg tablets every 12 hours

Main outcome variables
Fever; Lymphocyte count; ESR

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200404046935N1**
Registration date: **2020-04-20, 1399/02/01**
Registration timing: **registered_while_recruiting**
Last update: **2020-04-20, 1399/02/01**
Update count: **0**

Registration date
2020-04-20, 1399/02/01

Registrant information

Name
Farhang Babamahmoodi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 11 4221 8231

Email address
farhang.baba@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-04-18, 1399/01/30

Expected recruitment end date
2020-06-19, 1399/03/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of the effect of herbal medicine containing Saatar, Hofarigon and Fennel on reduction of pulmonary complications of COVID-19 in patients: a clinical trial

Public title
Effect of herbal medicine containing Saatar, Hofarigon and Fennel on COVID-19 patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Temperatures above 2 degrees Lymphocyte count less than 2 CRP positive Respiratory symptoms Symptoms of pulmonary involvement in CT scan Satisfaction to participate in the study Age older than 18 years

Exclusion criteria:

Oral intolerance Pulmonary disease

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be enrollment after admission and then divided into two groups by odd and even number. Patients with even numbers will receive herbal medicine and patients with even numbers will assigned in control group. This study has no concealment.

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 University of Medical Sciences

Street address

Moallem

City

Sari

Province

Mazandaran

Postal code

4817844718

Approval date

2020-03-18, 1398/12/28

Ethics committee reference number

IR.MAZUMS.REC.1398.1457

Health conditions studied

1

Description of health condition studied

COVID-19

ICD-10 code

B34.2

ICD-10 code description

Coronavirus infection, unspecified

Primary outcomes

1

Description

fever

Timepoint

Every day for 7 days

Method of measurement

termometer

2

Description

Lymphocyte count

Timepoint

Before and 7 days after intervention

Method of measurement

Cell counter device

3

Description

Erythrocyte sedimentation rate

Timepoint

Before and 7 days after intervention

Method of measurement

ESR device

Secondary outcomes

1

Description

Pneumonia

Timepoint

Before and 14 days after intervention

Method of measurement

CT-Scan

Intervention groups

1

Description

Intervention group: Kaletra 200 mg/50 mg tablet every 12 hours + hydroxychloroquine 200 mg tablets every 12 hours + herbal medicine containing sage, hofariqun and fennel (5 ml 3 times a day)

Category

Treatment - Drugs

2

Description
Control group: Kaletra 200 mg/50 mg tablet every 12 hours + hydroxychloroquine 200 mg tablets every 12 hours
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Razi Hospital in Ghaemshahr
Full name of responsible person
Farhang Babamahmoodi
Street address
Yousefreza
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4765686743
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
Majid Saeidi
Street address
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Postal code
4817844718
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majsaeedi@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mazandaran 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
Mazandaran University of Medical Sciences
Full name of responsible person
Farhang Babamahmoodi
Position
Professor
Latest degree
Specialist
Other areas of specialty/work
Infectious diseases
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

Yes - There is 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

Not applicable

Title and more details about the data/document

SPSS data can be shared

When the data will become available and for how long

After publication

To whom data/document is available

Researcher

Under which criteria data/document could be used

For use in meta-analysis studies

From where data/document is obtainable

Request to scientific corresponding

What processes are involved for a request to access data/document

By sending an email

Comments