

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 2026

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

City

Ghaemshahr

Province

Mazandaran

Postal code

4765686743

Phone

+98 11 4221 8018

Email

farhang.baba@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Majid Saeidi

Street address

Moallem

City

Sari

Province

Mazandaran

Postal code

4817844718

Phone

+98 11 3325 7230

Email

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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Person responsible for scientific inquiries

Contact

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Farhang Babamahmoodi

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Professor

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Person responsible for updating data

Contact

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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