

# 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 received 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

**Street address**

Yousefreza

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**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Mazandaran University of Medical Sciences

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Professor

**Latest degree**

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## Person responsible for updating data

**Contact**

**Name of organization / entity**

Mazandaran University of Medical Sciences

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Farhang Babamahmoodi

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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**