

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Sep 2026

Evaluation of herbal compound containing *Anacyclus pyrethrum*, *Senna*, *Ferrula asafoetida* and *Terminalia chebula* in COVID19: A randomized clinical trial study

Protocol summary

Study aim

Evaluation of the herbal supplements containing *Anacyclus pyrethrum*, *Senna*, *Ferrula asafoetida* and *Terminalia chebula* in COVID19

Design

Clinical trials with intervention and control groups, double-blind, randomized, phase 2-3 on 200 patients. "randomizer.org" will be used for randomization.

Settings and conduct

The clinical condition of the patients will be evaluated regularly in terms of improvement of the symptoms or the occurrence of possible complications. This will be done by registering the cases in the patients' files and examining them by the project executors, and at the end of the study, the data will be analyzed by statistical methods. The project will be implemented within Imam Reza (AS) Hospital in Tabriz.

Participants/Inclusion and exclusion criteria

Entrance criteria: Age over 18 years Positive findings of PCR or CT scan based on COVID-19 disease Tendency to attend a clinical trial study The severity of the disease is mild to moderate Exclusion criteria: Patients with severe disease status Liver disease experience Pregnancy or breastfeeding Kidney failure Kidney transplantation experience Receiving any clinical trial medication in the last 30 days

Intervention groups

Both groups of patients will receive standard treatment based on the national protocol (200 mg Hydroxychloroquine tablets or 250 mg Chloroquine phosphate tablets). The pill will be taken for a minimum of 7 days and a maximum of 14 days. In addition to standard treatment, patients in the intervention group will receive herbal supplement containing *Anacyclus pyrethrum*, *Senna*, *Ferrula asafoetida* and *Terminalia chebula* which is formulated as tablets, three times a day. In the control group, patients will receive only

standard treatment.

Main outcome variables

Reduction of the number of hospitalization days;
Improvement of the symptoms in a lesser time;
Reduction of the costs of care and hospital treatment

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200522047545N1**
Registration date: **2020-08-05, 1399/05/15**
Registration timing: **registered_while_recruiting**

Last update: **2020-08-05, 1399/05/15**

Update count: **0**

Registration date

2020-08-05, 1399/05/15

Registrant information

Name

Ramin Mohammadzadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 41 3557 1204

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-07-31, 1399/05/10

Expected recruitment end date

2020-09-21, 1399/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of herbal compound containing Anacyclus pyrethrum, Senna, Ferrula asafoetida and Terminalia chebula in COVID19: A randomized clinical trial study

Public title

Evaluation of herbal compound containing Anacyclus pyrethrum, Senna, Ferrula asafoetida and Terminalia chebula in COVID19

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age: more than 18 Lab Analysis and CT-scan Patient consent The severity of the disease: mild to moderate

Exclusion criteria:

Patients with severe disease status Liver disease experience Pregnancy or breastfeeding Kidney failure Kidney transplantation experience Receiving any clinical trial medication in the last 30 days

Age

From **18 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant

Sample size

Target sample size: **200**

Randomization (investigator's opinion)

Randomized

Randomization description

By visiting randomizer.org and selecting Generate numbers, 200 numbers in the range of 1000 to 100,000 will be created for the list of patients. Then the odd or even numbers will be selected as the intervention group.

Blinding (investigator's opinion)

Single blinded

Blinding description

The appearance of the placebo is formulated exactly like the main drug, so the patients will not be aware whether they are taking the original medicine or placebo.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Tabriz University of Medical Sciences

Street address

Daneshghsh

City

Tabriz

Province

East Azarbaijan

Postal code

5164414766

Approval date

2020-05-18, 1399/02/29

Ethics committee reference number

IR.TBZMED.REC.1399.126

Health conditions studied**1****Description of health condition studied**

COVID19

ICD-10 code

U07.1

ICD-10 code description

COVID-19

Primary outcomes**1****Description**

Decreasing hospital stay days

Timepoint

At the end of the study

Method of measurement

Based on the date of hospitalization and discharge from the hospital

2**Description**

Decreasing duration of symptoms presence

Timepoint

During and at the end of the study

Method of measurement

Based on the date of hospitalization and the date of dissolving of fever and improving of respiratory symptoms including dyspnea, cough and improving of O2 saturation during daily history taking and physical exams.

3**Description**

Hospital care and treatment costs

Timepoint

At the end of the study
Method of measurement
Based on patients' financial records (hospital stay days and etc.)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In addition to the standard treatment (200 mg Hydroxychloroquine tablets or two 250 mg Chloroquine phosphate tablets), herbal tablets containing Anacyclus pyrethrum, Senna, Ferrula asafoetida and Terminalia chebula will be taken in three tablets three times a day for 7 to 14 days.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Tabriz Imam Reza Hospital

Full name of responsible person

Mojtaba Varshouchi Fard

Street address

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varshochim@tbzmed.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Mohammad Samiei

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Samiei.moh@gmail.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Ramin Mohammadzadeh

Position

PhD Student in Pharmaceutics

Latest degree

Medical doctor

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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Mojtaba Varshouchi Fard

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

Contact
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Full name of responsible person
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Research Article
When the data will become available and for how long
Access start in 2021
To whom data/document is available
General
Under which criteria data/document could be used
Web service
From where data/document is obtainable
Journal website
What processes are involved for a request to access data/document
Web
Comments