Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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)

Phone
+98 41 3557 1204

Email address
mohammadzadeh.ra@tbzmed.ac.ir

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 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 dyspenea, 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

Daneshghah

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Tabriz

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5164414766

Phone

+98 41 3337 0094

Email

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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5164414766

Phone

+98 41 3335 7310

Email

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

Medical Pharmacy

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Mojtaba Varshouchi Fard

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Infectious diseases

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Person responsible for updating data

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
Medical Pharmacy

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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