Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The effect of herbal drugs (Echinacea and Ginger) on Improvement of clinical symptoms and hospitalizations in suspected COVID-19 outpatient cases

Protocol summary

Study aim
The effect of herbal drugs (Echinacea and Ginger) on Improvement of clinical symptoms and hospitalizations in suspected COVID-19 outpatient cases

Design
Controlled clinical trial with parallel group, single-blind, randomized,

Settings and conduct
This study will be conducted at the Mostafa Khomeini Comprehensive Health Center affiliated with Saveh University of Medical Sciences. In addition to standard treatment, 50 outpatients with suspected Qovid 19 outpatient treatment receive oral herbal remedies (echinacea and ginger) orally for 7 days. Fifty outpatients with suspected Qovid 19 control groups receive only standard treatment.

Participants/Inclusion and exclusion criteria
Inclusion criteria suspected COVID-19 outpatient cases according to the flowchart for the Diagnosis and Treatment of 19 COVID Diseases of the Ministry of Health, Age between 18 and 65 years, Signing a Informed Consent Exclusion criteria Pregnancy, Breastfeeding, history of drug allergy, complications of bacterial infection, underlying diseases (heart disease, renal failure, liver failure, primary vascular and cardiovascular disease, chronic lung disease, malignancy, endocrine and metabolic diseases, thyroid disorders) Immune system defects, encephalopathy, neuropathy

Intervention groups
suspected COVID-19 outpatient cases

Main outcome variables
Improvement of clinical symptoms and hospitalizations

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200415047089N1**
Registration date: **2020-04-19, 1399/01/31**
Registration timing: **registered_while_recruiting**

Last update: **2020-04-19, 1399/01/31**
Update count: **0**

Registration date
2020-04-19, 1399/01/31

Registrant information

Name
مهدی Mehdi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 86 4222 4414

Email address
mesrimd@gmail.com

Recruitment status
Recruitment complete

Funding source

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

Expected recruitment end date
2020-05-09, 1399/02/20

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of herbal drugs (Echinacea and Ginger) on

Improvement of clinical symptoms and hospitalizations in suspected COVID-19 outpatient cases

Public title

The effect of herbal drugs (Echinacea and Ginger) on Improvement of clinical symptoms and hospitalizations in suspected COVID-19 outpatient cases

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

suspected COVID-19 outpatient cases according to the flowchart for the Diagnosis and Treatment of 19 COVID Diseases of the Ministry of Health, Age between 18 and 65 years, Signing a Informed Consent

Exclusion criteria:

Pregnancy, Breastfeeding, history of drug allergy, complications of bacterial infection, underlying diseases (heart disease, renal failure, liver failure, primary vascular and cardiovascular disease, chronic lung disease, malignancy, endocrine and metabolic diseases, thyroid disorders) Immune system defects, encephalopathy, neuropathy

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, patients will be randomly assigned to each of the two treatment groups using a 1: 1 block randomization method.

Blinding (investigator's opinion)

Single blinded

Blinding description

Patients and physicians in charge of treating the patient will not go blind and will be aware of the intervention group. The researcher responsible for evaluating the results and the statistical analyst will be blind to the treatment group.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Saveh University of Medical Sciences

Street address

Saveh, at the beginning of Jomhouri Street, Saveh School of Medical Sciences

City

Saveh

Province

Markazi

Postal code

3919676651

Approval date

2020-03-28, 1399/01/09

Ethics committee reference number

IR.SAVEHUMS.REC.1399.004

Health conditions studied

1

Description of health condition studied

COVID 19

ICD-10 code

U07.1

ICD-10 code description

U07.1

Primary outcomes

1

Description

Improvement of clinical symptoms

Timepoint

Start of study and 7 days after study

Method of measurement

Questionnaire - telephone follow-up and

Secondary outcomes

1

Description

hospitalizations

Timepoint

7 and 14 days after study

Method of measurement

Telephone follow up

Intervention groups

1

Description

Intervention group: In this study, 2 herbal medicines (in addition to standard treatment) will be used as follows. 1. Vomigone 500 tablets (containing ginger) 2 TDS a day (after meals) With drug registration number: 9406633051781240 Dineh Pharmaceutical Company .2

Rucoldup tablets 750 (containing echinacea) 1 tablet TDS day with drug registration number: 6563916081842893 Company: Ghaem Daru

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

مرکز جامع سلامت مصطفی خمینی ساوه

Full name of responsible person

hamidreza koohestani

Street address

Saveh - At the beginning of Jomhuri Street

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9177899191

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+98 86 4234 3395

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Koohestani709@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Saveh University of Medical Sciences

Full name of responsible person

sasan gazerani

Street address

Saveh, at the beginning of Jomhouri Street, Saveh School of Medical Sciences

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3918698786

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Email

hamidnbkb@yahoo.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Saveh 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

Saveh University of Medical Sciences

Full name of responsible person

mehdi mesri

Position

هیات علمی

Latest degree

Specialist

Other areas of specialty/work

Forensic Medicine

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Saveh University of Medical Sciences

Full name of responsible person

mehdi mesri

Position

faculty member

Latest degree

Specialist

Other areas of specialty/work

Traditional medicine

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Province

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3919676651

Phone

42224414

Email

mesrimd@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Saveh University of Medical Sciences

Full name of responsible person
hamidreza koohestani

Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Medical Education

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
All potential data can be shared after people have not been identified.

When the data will become available and for how long
Access to the data after the publication of results

To whom data/document is available
Data will be available to researchers working at academic and scientific institutions.

Under which criteria data/document could be used
According to the ethics committee of the university, a decision will be made.

From where data/document is obtainable
It is possible through correspondence with the Vice Chancellor for Research
email.savehresearch@savehums.ac.ir

What processes are involved for a request to access data/document
It is possible through correspondence with the Vice Chancellor for Research of the University and after the decision in the University Ethics Council (about 1 month).

Comments