Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of Heilichrysum pseudoplicatum-syrupe on clinical manifestations and Para clinical features in patients with COVID-19: A Randomized clinical trial.

Protocol summary

Study aim
The effect of H.pseudoplicatum-syrup on clinical presentation and respiratory infection of patients with COVID-19

Design
This study is a clinical trial. In this study, there are two groups which consist of the experimental group (receive H.pseudoplicatum-syrup) and the control group (receive the routine treatment). The number of people in each group is 30. This is a single blind study, which statistical analyzers do not know about data and drugs.

Settings and conduct
The study site is in the Arak University of Medical Sciences. First of all, fatigue, anorexia, oxygen saturation, and blood pressure of patients will be measured. If they have the conditions of study, they will randomly divide into two groups. One group receives H.pseudoplicatum-syrup and the other group receives routine treatment. This study is a single blind study which statistical analyzers do not have knowledge about groups. At the end of the 2-week intervention phase, fatigue, anorexia, oxygen saturation and blood pressure in these patients will be measured again and the effectiveness of H.pseudoplicatum-syrup will be compared with the control group.

Participants/Inclusion and exclusion criteria
Inclusion criteria include: "Having informed consent to participate in the study, definitive diagnosis of COVID-19 and not attending in another clinical trial." exclusion criteria include: "Patient willingness to accept other therapies

Intervention groups
Drug group: Syrup based on the H.pseudoplicatum, which is produced with a concentration of 10% aqueous extract of H.pseudoplicatum, is prescribed for 2 weeks 3 times a day, 5 ml each time, a total of 15 ml daily. This syrup is made by Traditional and Complementary Medicine Research Center of Arak University of Medical Sciences. Control group: takes routine drugs.

Main outcome variables
Fatigue, anorexia, oxygen saturation and blood pressure

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180610040049N6**
Registration date: **2020-12-04, 1399/09/14**
Registration timing: **retrospective**

Last update: **2020-12-04, 1399/09/14**
Update count: **0**

Registration date
2020-12-04, 1399/09/14

Registrant information

Name
Amirhosein Latifi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 86 3417 3601

Email address
Sah.latifi@arakmu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-05-18, 1399/02/29

Expected recruitment end date
2020-06-18, 1399/03/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Heilichrysum pseudoplicatum-syrupe on clinical manifestations and Para clinical features in patients with COVID-19: A Randomized clinical trial.

Public title

The effect of Heilichrysum pseudoplicatum-syrupe on clinical manifestations of patients with COVID-19

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Having informed consent to participate in the study The definitive diagnosis of COVID-19 Failure to attend another clinical trial simultaneously

Exclusion criteria:

Patient's willingness to use other therapies Alzheimer's patients

Age

From **20 years** old to **70 years** old

Gender

Both

Phase

3

Groups that have been masked

- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

The present study is a simple randomized clinical trial on patients with COVID-19. In this study, simple randomization method will be used. A randomized list will be generated by online randomization site (sealedenvelope.com). Individuals will be allocated to intervention or control group according to the list.

Blinding (investigator's opinion)

Single blinded

Blinding description

The drug group is given Heilichrysum pseudoplicatum-syrupe and the control group receives their routine medications. The statistical analyst is not informed about the groups.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Arak University of Medical Sciences

Street address

Arak University of Medical Sciences,Basij Square

City

Arak

Province

Markazi

Postal code

3848176941

Approval date

2020-04-14, 1399/01/26

Ethics committee reference number

IR.ARAKMU.REC.1399.003

Health conditions studied

1

Description of health condition studied

Patients with Corona Virus

ICD-10 code

U07.1

ICD-10 code description

COVID-19, virus identified

Primary outcomes

1

Description

Fatigue

Timepoint

One day before the intervention and 2 weeks after the intervention is measured

Method of measurement

Using a fatigue questionnaire

2

Description

Anorexia

Timepoint

One day before the intervention and 2 weeks after the intervention is measured

Method of measurement

Using anorexia questionnaire

3

Description

Oxygen saturation

Timepoint

One day before the intervention and 2 weeks after the intervention is measured

Method of measurement

Using a pulse oximeter

4

Description
blood pressure
Timepoint
One day before the intervention and 2 weeks after the intervention is measured
Method of measurement
Using a sphygmomanometer

Secondary outcomes

empty

Intervention groups

1

Description
"Intervention group:" This group consumes the Heilichrysum pseudoplicatum-syrupe. The concentration of this syrup is 10% of the aqueous extract of Heilichrysum pseudoplicatum-syrupe. This syrup is administered three times daily for two weeks, 5 ml each time, a total of 15 ml daily. This syrup is made by Shahid Beheshti School of Pharmacy and Traditional and Complementary Medicine Research Center of Arak University of Medical Sciences.
Category
Treatment - Drugs

2

Description
Control group: This group only receives their routine drugs.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Arak Valiasr Hospital
Full name of responsible person
Hosein Sarmadian
Street address
Valiasr Hospital, Imam St, Arak
City
Arak
Province
Markazi
Postal code
3848176341
Phone
+98 86 3417 3645
Email
hosseinsarmadian2015@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Alireza Kamali
Street address
Arak University of Medical Sciences, Basij Square, Arak
City
Arak
Province
Markazi
Postal code
3848176941
Phone
+98 86 3417 3645
Email
research@arakmu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Arak 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
Arak University of Medical Sciences
Full name of responsible person
Hosein Sarmadian
Position
Associate Professor
Latest degree
Specialist
Other areas of specialty/work
Infectious diseases
Street address
Arak University of Medical Sciences, Basij Square, Arak
City
Arak
Province
Markazi
Postal code

3848176941

Phone
+98 86 3417 3601

Email
hosseinsarmadian2015@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Mohammad KamaliNejad

Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Traditional Medicine

Street address
Shahid Beheshti School of Pharmacy, Valiasr St, Tehran

City
Tehran

Province
Tehran

Postal code
6153- 14155

Phone
+98 21 8820 0118

Email
mkamalinejad@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Arak University of Medical Sciences

Full name of responsible person
Seied Amirhosein Latifi

Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Traditional Medicine

Street address
Arak University of Medical Sciences,Basij Square, Arak

City
Arak

Province
Markazi

Postal code
3848176941

Phone
+98 86 3417 3601

Email
seiedalatifi@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
No more information

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
Not applicable

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
Not applicable

Data Dictionary
Not applicable