Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Nov 2026

Effect of Laris - Hyssop combined herbal distilled on the improving clinical and paraclinical symptoms in patients with COVID-19: A Randomized Controlled Trial

Protocol summary

Study aim
Evaluation of the effects of Laris-Hyssop distillate on improving clinical and paraclinical symptoms of COVID-19 patients.

Design
A randomized controlled, triple blinded clinical trial with a parallel-group design of 80 patients, which allocated to trial groups using Random Allocation Software (RAS)

Settings and conduct
This study is a randomized controlled triple blinded trial that will be conducted on COVID-19 patients who referred to Imam Reza and Sinai Educational-Medical Center Hospitals of Tabriz University of Medical Sciences in two groups (intervention and control groups). The patients, researcher, and statistical analyst will be blind to the received active drug or placebo. Participants will be allocated to trial groups randomly using Random Allocation Software (RAS). Patients will receive a sealed bottle containing Laris-Hyssop distillate or placebo by giving 10 ml every 8 hours for 14 days. Both groups will receive routine treatments.

Participants/Inclusion and exclusion criteria
In this study, all patients aged 15 years and older with COVID-19 who had newly admitted to the hospital, signed an informed consent form to participate in the study, and not participate in another clinical trial simultaneously will be included.

Intervention groups
In the intervention group, participants will receive Laris-Hyssop distillate (including hyssop, Echium amoenum, Adiantum capillus-veneris, Hollyhocks, Eucalyptus, Malva, Platanus, chamomilla), 10 ml every 8 hours for 14 days. The control group will receive a placebo (no therapeutic value), resembled the Laris-Hyssop distillate with the same prescription. Both groups will receive routine treatments.

Main outcome variables
Respiratory Rate (RR); Oxygen saturation (SpO2); Serum white blood cell count; serum CRP level; the number of inpatient days; Mortality

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200518047497N1**
Registration date: **2020-05-21, 1399/03/01**
Registration timing: **prospective**

Last update: **2020-05-21, 1399/03/01**
Update count: **0**

Registration date
2020-05-21, 1399/03/01

Registrant information

Name
Javad Amadian Heris

Name of organization / entity

Country
Iran (Islamic Republic of)

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Email address
ahmadianj@tbzmed.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-05-25, 1399/03/05

Expected recruitment end date
2020-07-20, 1399/04/30

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effect of Laris - Hyssop combined herbal distilled on the improving clinical and paraclinical symptoms in patients with COVID-19: A Randomized Controlled Trial

Public title
Effect of Laris - Hyssop combined herbal distilled on the improving clinical and paraclinical symptoms in patients with COVID-19
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
COVID-19 patients aged 15 years and older Newly admitted people (first day of hospitalization) Obtaining informed consent to participate in the trial Non-participation in another clinical trial simultaneously
Exclusion criteria:
Epilepsy Having liver or kidney failure according to the patient's statement, and doctor examination or based on creatinine, SGOT, SGPT, LDH tests. Having a chronic disease (cardiovascular disease, uncontrolled high blood pressure (hypertension above 160/100 despite taking medication), complicating diabetes, respiratory diseases, BMI> 40 according to the patient's statement, and doctor examination Immunodeficiency (treated with Corticosteroids over 12.5 mg / d Prednisolone for more than two weeks, chemotherapy, malignancies, organ transplants, HIV patients, other viral diseases) Pregnancy (according to the patient's statement and examination by a doctor) Breastfeeding (according to the patient's statement)
Age
From **15 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size
Target sample size: **80**
Randomization (investigator's opinion)
Randomized
Randomization description
Participants will be allocated to trial groups (intervention and placebo groups) randomly using Random Allocation Software (RAS) trough random block sizes of 4 and 6 with an allocation ratio of 1:1. Patients will receive a sealed bottle containing Laris-Hyssop distillate or placebo by giving 10 ml every 8 hours for 14 days. Random sequencing allocation will be produced by the person who has not to participate in the research. Bottles will be numbered from 1 to 80 according to the sequence generated. Both groups will receive routine treatments
Blinding (investigator's opinion)
Triple blinded
Blinding description
This study is a randomized controlled triple blinded trial, meaning that the patients, researcher, and statistical analyst will be blind to the received active drug or placebo. Random sequencing allocation will be produced by the person who has not to participate in the research. Each participant will receive a sealed bottle containing Laris-Hyssop distillate or placebo by giving 10 ml every 8 hours for 14 days.
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
No 2 Central Building, Tabriz University of Medical Sciences, University Street, Tabriz
City
Tabriz
Province
East Azarbaijan
Postal code
5165665931
Approval date
2020-04-13, 1399/01/25
Ethics committee reference number
IR.TBZMED.REC.1399.027

Health conditions studied

1

Description of health condition studied
COVID-19
ICD-10 code
U07.01
ICD-10 code description
Novel Cronavirus Disease (COVID-19)

Primary outcomes

1

Description
Respiratory Rate
Timepoint

Daily
Method of measurement
Observation

2

Description
Oxygen saturation (SpO2)
Timepoint
Daily
Method of measurement
Pulse Oximeter

3

Description
Serum White Blood Cell count
Timepoint
Before- After intervention (14 days)
Method of measurement
laboratory cell counter

4

Description
Serum CRP level
Timepoint
Before-After intervention (14 days)
Method of measurement
Biochemical method

5

Description
Number of inpatient days
Timepoint
After intervention
Method of measurement
Questionnaire

6

Description
Mortality
Timepoint
Daily
Method of measurement
Questionnaire

Secondary outcomes

1

Description
The time of absence of dry Cough
Timepoint
Daily
Method of measurement
Daily symptom questionnaire

2

Description
The time of absence of trembling
Timepoint
Daily
Method of measurement
Daily symptom questionnaire

3

Description
The time of absence of sore throat
Timepoint
Daily
Method of measurement
Daily symptom questionnaire

4

Description
The time of absence of difficulty breathing or shortness of breath
Timepoint
Daily
Method of measurement
Daily symptom questionnaire

5

Description
The time of absence of temperature equal to or grater than 37/8 C
Timepoint
Daily
Method of measurement
Daily symptom questionnaire

6

Description
Body temperature
Timepoint
Daily
Method of measurement
Thermometer

7

Description
Negative unilateral infiltration
Timepoint
After intervention
Method of measurement
Radiography- CT SCAN

8

Description
Negative bilateral infiltration
Timepoint
After intervention
Method of measurement
Radiography- CT SCAN

Intervention groups

1

Description
Intervention group: In the intervention group, participants will receive Laris-Hyssop distillate (including hyssop, Echium amoenum, Adiantum capillus-veneris, Hollyhocks, Eucalyptus, Malva, Platanus, chamomilla), 10 ml every 8 hours for 14 days orally. Both groups will receive routine treatments.
Category
Treatment - Drugs

2

Description
Control group: The control group will receive a placebo (no therapeutic value), resembled the Laris-Hyssop distillate with the same prescription. Both groups will receive routine treatments.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Reza Hospital
Full name of responsible person
Javad Ahmadian heris
Street address
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2

Recruitment center
Name of recruitment center
Sina Hospital
Full name of responsible person
Javad Ahmadian heris
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East Azerbaijan Province, Tabriz, North West Medical Toxicology Center
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
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Web page address
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
Javad Ahmadian heris
Position
Professor assistant of allergy and clinical immunology
Latest degree
Subspecialist
Other areas of specialty/work
Pediatrics
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Professor assistant of allergy and clinical immunology

Latest degree
Subspecialist

Other areas of specialty/work
Pediatrics

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Person responsible for updating data

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Full name of responsible person
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Nutrition

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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
Not applicable

Informed Consent Form
Undecided - It is not yet known if there will be 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
The effects of Laris-Hyssop distillate on improving clinical and paraclinical symptoms of COVID-19 patients

When the data will become available and for how long
End of July

To whom data/document is available
healthcare professional- Professors

Under which criteria data/document could be used
An official request from the organization

From where data/document is obtainable
Tabriz University of Medical Sciences

What processes are involved for a request to access data/document
Request to Vice-Chancellor for Research and Technology Affairs

Comments