Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Effect of Laris-Teucrium Polium L.and Laris-Hyssop combined herbal medicine on the prevention of covid-19 disease in high risk people exposed for corona virus: A randomized controlled field trial.

Protocol summary

Study aim

Determining the effect of combined herbal medicines on Polium and Hisspus on the prevention of coronavirus in healthy people exposed to coronavirus patients

Design

Clinical trial with control group, with parallel groups, three-way blind, randomized, phase 3 on 300 individuals. RAS software was used for randomization.

Settings and conduct

This study is a three-way blind clinical trial in which the target population is high-risk families exposed to the coronavirus in Tabriz. Two herbal medicines, polioum, hisspus and placebo, will be used in three intervention groups at a daily dose of 10 cc for 20 days. Medicines and placebo are prepared in similar bottles of 500 ml. Blinding is done for the researcher, the patient, and the analyzer.Tracking of the status of people taking the drug will be done every five days by phone call and filling out the information form about the occurrence or non-occurrence of coronary artery disease symptoms and the possible occurrence of side effects caused by drug use. The research results will be statistically analyzed using SPSS version 21 / software.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1) High-risk people exposed to the coronavirus 2) Age 7 years and older 3) Having a conscious consent form signed to participate in the study 4) Lack of simultaneous participation in other clinical trials Exclusion criteria: 1) People with suspicious, probable or definite symptoms of the disease and need hospitalization or receiving Corona medication on an outpatient basis and their families 2) Pregnant women 3) Breastfeeding women 4) Having liver or kidney failure

Intervention groups

Intervention groups include three groups receiving Polium, Hisspus, and placebo.

Main outcome variables

The incidence of dry cough, fever, sore throat, shortness of breath, shivering, proprietary testing positive for coronavirus

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200503047280N1**
Registration date: **2020-06-02, 1399/03/13**
Registration timing: **registered_while_recruiting**

Last update: **2020-06-02, 1399/03/13**
Update count: **0**

Registration date

2020-06-02, 1399/03/13

Registrant information

Name

Seyyed mohammad bagher Fazljou

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3337 9527

Email address

fazljoum@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-05-09, 1399/02/20

Expected recruitment end date

2020-07-10, 1399/04/20

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effect of Laris-Teucrium Polium L.and Laris-Hyssop combined herbal medicine on the prevention of covid-19 disease in high risk people exposed for corona virus: A randomized controlled field trial.

Public title
Effect of Laris-Teucrium Polium L.and Laris-Hyssop combined herbal medicine on the prevention of covid-19 disease
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
High-risk people exposed to the corona virus Older than 7 years Having an informed consent form to participate in the study Not participation in another simultaneous clinical trial
Exclusion criteria:
Pregnant women Breastfeeding women Having liver or renal failure, according to the individual or family declaration
Age
From **7 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **300**
Randomization (investigator's opinion)
Randomized
Randomization description
Six and nine blocking with allocation ratio of 1: 1: 1 into three groups consisting of two intervention groups and one control group Darnma using computer software RAS (Random Allocation Software)
Blinding (investigator's opinion)
Triple blinded
Blinding description
Laris-Teucrium Polium L.and Laris-Hyssop, and placebo drugs will be prepared in exactly similar 500 ml bottles and will be numbered based on random allocation sequences. Drug recipients, researchers, data analysts, and data monitoring and safety boards will be blind to the received intervention.
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
Faculty of Traditional Medicine, Tabriz University of Medical Sciences
City
Tabriz
Province
East Azarbaijan
Postal code
5165665931
Approval date
2020-04-21, 1399/02/02
Ethics committee reference number
IR.TBZMED.REC.1399.026

Health conditions studied

1

Description of health condition studied
COVID-19
ICD-10 code
U07.1
ICD-10 code description
COVID-19, virus identified

Primary outcomes

1

Description
Symptoms of corona-virus
Timepoint
Day 5, 10, 15 and 20 of the taking combined herbal medicine
Method of measurement
Corona-virus Symptoms Questionnaire

Secondary outcomes

1

Description
Side effects
Timepoint
During and at the end of intervention
Method of measurement

Side effects questionnaire

2

Description
Satisfaction with drug use
Timepoint
At the end of intervention
Method of measurement
Questionnaire

Intervention groups

1

Description
First intervention group: Laris-Tokrium polium compound herbal medicine. This compound will be prepared as a herbal distillate in 500 cc bottles by Sarab Production and Service Company. The appearance of the drug is designed to be the same in all three groups. Two will be given to each eligible person to take 5 (under 12 years) or 10 (over 12 years) CC of this drug orally daily between meals for 20 days. . Volunteers involved in the intervention of healthy people are exposed to the infected person and will not be sick to receive routine treatment. After the end of the consumption period, data collection and final analysis takes place.
Category
Prevention

2

Description
First intervention group: Laris-Tokrium Hisspus compound herbal medicine. This compound will be prepared as a herbal distillate in 500 cc bottles by Sarab Production and Service Company. The appearance of the drug is designed to be the same in all three groups. Two will be given to each eligible person to take 5 (under 12 years) or 10 (over 12 years) CC of this drug orally daily between meals for 20 days. . Volunteers involved in the intervention of healthy people are exposed to the infected person and will not be sick to receive routine treatment. After the end of the consumption period, data collection and final analysis takes place.
Category
Prevention

3

Description
Control group: placebo. The ineffective solution, which will be prepared by a fellow pharmacist, will be used in similar bottles and similar appearance specifications with drugs from other groups and with the same recipe. Volunteers involved in the intervention of healthy people are exposed to the infected person and will not be sick to receive routine treatment.After the end of the consumption period, data collection and final analysis takes place.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Tabriz Health Center
Full name of responsible person
Seyyed Mohammad Bagher Fazljou
Street address
Tabriz Health Center, Jahad Square,
City
Tabriz
Province
East Azarbaijan
Postal code
5165665931
Phone
+98 41 3337 9527
Email
dr.fazljou@ yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Mohammad samiei
Street address
Tabriz University of Medical Sciences
City
Tabriz
Province
East Azarbaijan
Postal code
5165665931
Phone
+98 41 3335 7310
Email
dr.fazljou@yahoo.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
Seyyed mohammad bagher fazljou

Position
Non-faculty physician

Latest degree
Ph.D.

Other areas of specialty/work
Traditional Medicine

Street address
Faculty of Traditional Medicine-Tabriz University of Medical Sciences

City
Tabriz

Province
East Azarbaijan

Postal code
5165665931

Phone
+98 41 3337 9527

Email
dr.fazljou@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
Seyyed mohammad bagher fazljou

Position
Non-faculty physician

Latest degree
Ph.D.

Other areas of specialty/work
Traditional Medicine

Street address
Faculty of Traditional medicine- Tabriz university of medical sciences

City
Tabriz

Province
East Azarbaijan

Postal code
5165665931

Phone
0098413339527

Email
dr.fazljou@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
Seyyed mohammad bagher fazljou

Position
Non-faculty physician

Latest degree
Ph.D.

Other areas of specialty/work
Traditional Medicine

Street address
Faculty of Traditional Medicine- Tabriz University of Medical Sciences -

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Tabriz

Province
East Azarbaijan

Postal code
5165665931

Phone
0098413339527

Email
dr.fazljou@yahoo.com

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
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

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
Undecided - It is not yet known if there will be a plan to make this available