Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effect of Cinnamase drops on the incidence of clinical symptoms in asymptomatic individuals in the family of under treatment Covid 19 patients

Protocol summary

Study aim
Effect of Cinnamase drops on the incidence of clinical symptoms in asymptomatic individuals in the family of under treatment Covid 19 patients

Design
The present study is a randomized controlled clinical trial involving two groups of intervention and control which is performed in parallel, non-blind, randomized groups by SAS9.4 software on 100 patients.

Settings and conduct
The study site is Kian Asai Pars Health Promotion and Prevention Center. By examining the PCR test, after a visit by a physician, individuals with the inclusion criteria complete an informed consent form. According to the table of random numbers, the intervention group received Cinnamaz drops and the control group did not receive medication. At the end of the intervention in the first week and second week, participants will be monitored for clinical symptoms and COVID-19. and a questionnaire approved by infectious and lung diseases researchers is completed for both groups

Participants/Inclusion and exclusion criteria
Inclusion criteria for participants are: Definitive diagnosis of Covid 19 for a member of family based on clinical symptoms and positive PCR test result; Signing an informed consent form; No symptoms of Covid 19 from two weeks before the study; Do not participate in other clinical trials and exclusion criteria is allergy to herbal medicines and natural oils.

Intervention groups
Intervention group: 50 healthy persons in contact with the Covid-19 patient use one drop of Cinnamase oil (License number: 118880/665, the product of "Sanabel Daroo" company, prepared from Nigella sativa L. oil and Olea europaea L oil.) in each side of their nose twice a day for 7 days. Control group: 50 healthy persons in contact with the Covid-19 patient do not take any complementary therapy during the study.

Main outcome variables
Clinical signs of coronavirus disease

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210515051305N1**
Registration date: **2021-07-10, 1400/04/19**
Registration timing: **registered_while_recruiting**

Last update: **2021-07-10, 1400/04/19**
Update count: **0**

Registration date
2021-07-10, 1400/04/19

Registrant information

Name
Zahra Bahaeddin

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 6646 4320

Email address
z.bahaedin@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-06-16, 1400/03/26

Expected recruitment end date
2022-05-22, 1401/03/01

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effect of Cinnamase drops on the incidence of clinical symptoms in asymptomatic individuals in the family of under treatment Covid 19 patients

Public title
The effect of Cinnamase drops on family members of patients with Covid 19
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Definitive diagnosis of Covid 19 for a member of family based on clinical symptoms and positive PCR test result. Signing consent form by volunteers participating in the study Volunteers should not have Covid-19 symptoms for two weeks prior to the study Volunteers should not participate in other clinical trials Volunteers should not use supplements (containing vitamins, minerals and probiotics) or other preventive treatments.
Exclusion criteria:
Allergy to herbal medicines and and natural oils
Age
No age limit
Gender
Both

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **100**
Randomization (investigator's opinion)
Randomized
Randomization description
Eligible participants will be randomly assigned into 2 groups in a 1:1 ratio using block randomization method with a block length of 2 by PROC PLAN of SAS 9.4. An independent statistician generates the randomization number sequence. The drug codes will be attached after the manufacturing and packaging of the experiment treatment and placebo. The drugs will be allocated sequentially according to the screening order of the patients. Group assignment will be kept in an opaque and sealed envelope and will be opened after data analysis by another statistician.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Shahed University
Street address
Shahed University, In front of the holy shrine of Imam Khomeini, Qom freeway,Tehran , Iran.
City
Tehran
Province
Tehran
Postal code
3319118651
Approval date
2021-04-27, 1400/02/07
Ethics committee reference number
ir.shahed.rec.1400.014

Health conditions studied

1

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

Primary outcomes

1

Description
Clinical signs of coronavirus disease
Timepoint
Before starting the study,7,14 days after the start of the study
Method of measurement
Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: 50 healthy persons in contact with the Covid-19 patient use one drop of Cinnamase oil in each side of their nose twice a day for 7 days. They should not take other complementary treatments during the study. The questionnaire is completed on days 0, 7

and 14. Cinnamase drops (License number: 118880/665) is the product of "Sanabel Daroo" company. This drug is a product derived from the knowledge of Iranian traditional medicine, which is scientifically prepared from Nigella sativa L. oil and Olea europaea L oil.

Category

Prevention

2

Description

Control group: 50 healthy people in contact with Covid-19 patients, who not taking any other complementary treatment during the study. The questionnaire is completed on days 0, 7 and 14.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Kian Asai Pars Health Promotion and Prevention Center

Full name of responsible person

Mohsen Naseri

Street address

No. 13, 1st Kouhestan, Pasdaran, Nobonyad Square, Tehran

City

Tehran

Province

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1963846451

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Email

info@advancedmed.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahed University

Full name of responsible person

Zahra Kiasalari

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Shahed University, In front of the holy shrine of Imam Khomeini, Qom freeway,Tehran , Iran.

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Email

itmrc@shahed.ac.ir

Web page address

http://shahed.ac.ir

Grant name

Grant code / Reference number

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

No

Title of funding source

Traditional Medicine Clinical Trial Research Center, Shahed University, Tehran, Iran

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

Shahed University

Full name of responsible person

Mohsen Naseri

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Traditional Medicine

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahed University

Full name of responsible person

Mohsen Naseri

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

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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

The study has not yet begun. The data has not been collected yet and it will be decided later, but the results will be published

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

Not applicable

Data Dictionary

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