

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 Jun 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

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**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

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**Full name of responsible person**

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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**

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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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**Latest degree**

Ph.D.

**Other areas of specialty/work**

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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