Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Study of the effect of Sinamaz on the prevention of upper respiratory diseases (URD) among Iranian arbaeen Pilgrims

Protocol summary

Study aim
Study of the effect of Sinamaz on the prevention of upper respiratory diseases (URD) among Iranian Arbaeen Pilgrims

Design
This study is a double-blind, randomized, placebo-controlled clinical trial on 180 healthy Iranian Arbaeen Pilgrims. 180 codes were randomized with Excel software.

Settings and conduct
The informed consent form is signed by the candidates participating in the study or their legal guardians if they have not reached the legal age. Relevant questionnaires are completed. Sinamaz and placebo are provided by the manufacturer with similar containers. Special codes are inserted on the package that will be kept confidential until the end of the study. Healthy Iranian Arbaeen Pilgrims use one drop in each side of their nose twice a day for 1 week. The questionnaire is completed on days 0 and The end of the trip

Participants/Inclusion and exclusion criteria
Signing consent forms by volunteers participating in the study; Volunteers should not have respiratory disease symptoms; Volunteers should not participate in other clinical trials; People who are suffering from certain underlying diseases or receiving drugs such as corticosteroids or immunosuppressants nor who have any history of nose or septum surgery are not approved as volunteers.

Intervention groups
90 healthy Iranian Arbaeen Pilgrims use one drop of Cinnamase oil in each side of their nose twice a day for 1 week. Sinamaz 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. Control group: 90 healthy Iranian Hajj Pilgrims use one drop of placebo on each side of their nose twice a day for 1 week.

Main outcome variables
Clinical signs of of upper respiratory diseases

General information

Reason for update
The doctors could not fill out the questionnaires.

Acronym
URD

IRCT registration information
IRCT registration number: **IRCT20210515051305N2**
Registration date: **2023-05-24, 1402/03/03**
Registration timing: **prospective**

Last update: **2024-09-14, 1403/06/24**
Update count: **1**

Registration date
2023-05-24, 1402/03/03

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
2023-07-23, 1402/05/01

Expected recruitment end date
2025-08-11, 1404/05/20

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Study of the effect of Sinamaz on the prevention of upper respiratory diseases (URD) among Iranian arbaeen Pilgrims

Public title
The effect of Sinamaz drops on the prevention of upper respiratory diseases among Iranian arbaeen Pilgrims
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Signing consent forms by volunteers participating in the study Volunteers should not have respiratory diseases symptoms Volunteers should not participate in other clinical trials people who are suffering from certain underlying diseases or receiving drugs such as corticosteroids or immunosuppressants nor who have any history of nose or septum surgery are not approved as Volunteers
Exclusion criteria:
Allergy to herbal medicines and and natural oils
Age
No age limit
Gender
Both

Phase
2
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **180**
More than 1 sample in each individual
Number of samples in each individual: **4**
Filling the questionnaire
Randomization (investigator's opinion)
Randomized
Randomization description
Eligible participants will be randomly assigned into 2 groups in a 1:1 ratio using a 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)
Double blinded
Blinding description
The coding is done in two groups and placebo by a person who does not interfere in the plan and keeps the codes confidential. Until the end of the study, the researcher, doctor and project colleagues are not aware of it.
Placebo
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
2023-05-08, 1402/02/18
Ethics committee reference number
IR.SHAHED.REC.1402.001

Health conditions studied

1

Description of health condition studied
Upper respiratory diseases
ICD-10 code
J39
ICD-10 code description
Other diseases of upper respiratory tract

Primary outcomes

1

Description
Clinical signs of of upper respiratory diseases
Timepoint
The questionnaire is completed on days 0, 3 and 7.
Method of measurement
Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: 90 healthy Iranian Arbaeen Pilgrims use one drop of Cinnamase oil in each side of their nose twice a day for 1 week. The questionnaire is completed on days 0, 3, and 7. Sinamaz 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
Treatment - Drugs

2

Description
90 healthy Iranian Arbaeen Pilgrims use one placebo drop on each side of their nose twice a day for 1 week. The questionnaire is completed on days 0 and 3, 7.

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
موکب

Full name of responsible person
Mohsen Naseri

Street address
No.1471, North Kargar Street, Enghelab Square,Tehran , Iran.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahed University

Full name of responsible person
Shahriar Bijani

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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
Professor

Latest degree
Ph.D.

Other areas of specialty/work
Traditional Medicine

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Person responsible for scientific inquiries

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Person responsible for updating data

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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
Yes - There is 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
Title and more details about the data/document
Clinical study report: published as an article.
When the data will become available and for how long
6 months after printing the results in the form of an article
To whom data/document is available
Researchers working in institutions and individuals in the industrial sector can apply to a scientific respondent.
Under which criteria data/document could be used
It is possible to use the documents after publishing the extracted article with a scientifically responsive opinion.
From where data/document is obtainable
Email: naseri@shahed.ac.ir naserishahed@yahoo.com
What processes are involved for a request to access data/document
The email will be reviewed by the applicant at least two days after the application is sent and will be answered within a week.
Comments