Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of the efficacy of nasal spray formulation containing eucalyptus tree oil in the treatment of seasonal allergic rhinitis: a randomized double-blind placebo-controlled clinical trial

Protocol summary

Study aim
Evaluation of the effectiveness of the nasal spray containing tea tree oil in the treatment of patients with seasonal allergic rhinitis

Design
Parallel group, double-blind, randomized controlled trial

Settings and conduct
This study is a double-blind clinical trial which will be conducted in an ear nose and throat clinic and an asthma and allergy clinic. Patients will be randomly assigned to the eucalyptus tree oil spray or placebo groups. Outcomes will be assessed at the initiation of the study and every day. The duration of the study is 2weeks. Assessor of the outcomes will not have any information about the assignment of patients.

Participants/Inclusion and exclusion criteria
Inclusion criteria: patients aged 18-65 years old who have seasonal allergic rhinitis confirmed by skin prick test Exclusion criteria: structural nose disorders, asthma, chronic obstructive pulmonary disorder, rhinosinusitis, chronic disorders like chronic kidney disease, liver failure, hypertension, diabetes mellitus, ischemic heart disease, malignancy, and systemic inflammatory disorders, respiratory infections in the previous 8 weeks, consumption of oral corticosteroids in the previous week, pregnancy, lactation, patients who are receiving immunotherapy or have a history of immunotherapy

Intervention groups
Intervention group 1: patients will receive a puff of the nasal spray containing eucalyptus tree oil two times per day. Intervention group 2: patients will receive a puff of the placebo nasal spray, which is similar to the eucalyptus tree oil spray in shape, size, and color but contains 0.9% sodium chloride, two times per day.

Main outcome variables
The score of total nasal symptom score (TNSS) questionnaire

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210718051920N1**
Registration date: **2021-07-31, 1400/05/09**
Registration timing: **registered_while_recruiting**

Last update: **2021-07-31, 1400/05/09**
Update count: **0**

Registration date
2021-07-31, 1400/05/09

Registrant information

Name
hamid forootanfar

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 34 3132 5238

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-07-27, 1400/05/05

Expected recruitment end date
2021-12-26, 1400/10/05

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of the efficacy of nasal spray formulation containing eucalyptus tree oil in the treatment of seasonal allergic rhinitis: a randomized double-blind placebo-controlled clinical trial

Public title
Evaluation of the efficacy of nasal spray formulation containing eucalyptus tree oil in the treatment of seasonal allergic rhinitis

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
seasonal allergic rhinitis confirmed by skin prick test

Exclusion criteria:
Structural disorders of the nose such as nasal polyps, nasal deviation and other structural disorders Asthma Chronic obstructive pulmonary disease (COPD) Rhinosinusitis Chronic diseases such as kidney failure, liver failure, hypertension, diabetes, ischemic heart disease, Malignancy, and systemic inflammatory diseases Respiratory infections during the previous 8 weeks Use of oral corticosteroids during the previous week pregnancy lactation Patients who are receiving immunotherapy or have a history of immunotherapy

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **70**

Randomization (investigator's opinion)
Randomized

Randomization description
Blocked randomization will be done using randomly selected block sizes of 4, 6 and 8. For example a block size of 4 randomizes 4 participants, and each participant is assigned to one of the intervention or control groups based on the arranged series of the groups in this block. The researcher evaluating the patients will not be aware of the sizes of blocks and sequence of their selection.

Blinding (investigator's opinion)
Double blinded

Blinding description
The patients and investigators who evaluate therapeutic responses of the patients and who analyzes the results will be blinded.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Kerman University of Medical Sciences

Street address
Research assistance office of Kerman University of Medical Sciences, Ebne-sina Ave., Jahad Blvd. Kerman City

City
Kerman

Province
Kerman

Postal code
7619813159

Approval date
2021-07-12, 1400/04/21

Ethics committee reference number
IR.KMU.REC.1400.227

Health conditions studied

1

Description of health condition studied
Seasonal allergic rhinitis

ICD-10 code
J30.2

ICD-10 code description
Other seasonal allergic rhinitis

Primary outcomes

1

Description
The severity of the symptoms of seasonal allergic rhinitis

Timepoint
At the initiation of the study and every day

Method of measurement
Total nasal symptom score (TNSS)

Secondary outcomes

1

Description
Control of the symptoms of seasonal allergic rhinitis

Timepoint
At the beginning of the study and at the end of the first and second weeks of the study

Method of measurement
Rhinitis Control Assessment Test questionnaire

2

Description
Quality of life

Timepoint
At the beginning of the study and at the end of the first and second weeks of the study
Method of measurement
Mini rhinoconjunctivitis quality of life questionnaire (Mini RQLQ)

Intervention groups

1

Description
Intervention group: Intervention group 1: patients will receive a puff of the nasal spray containing eucalyptus tree oil two times per day.
Category
Treatment - Drugs

2

Description
Control group: Intervention group 2: patients will receive a puff of the placebo nasal spray, which is similar to the eucalyptus tree oil spray in shape, size, and color but contains 0.9% sodium chloride, two times per day
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Asthma and allergy clinic
Full name of responsible person
Gholamreza Sedighi
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2

Recruitment center
Name of recruitment center
Ear nose and throat clinic
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Sponsors / Funding sources

1

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Name of organization / entity
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Grant name
Grant code / Reference number
400000100
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Kerman 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
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Hamid Forootanfar
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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
There is no further information.
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not 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
Not applicable