

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Evaluation of the efficacy of nasal spray formulation containing tea 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 tea 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 tea tree oil two times per day. Intervention group 2: patients will receive a puff of the placebo nasal spray, which is similar to the tea 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: **IRCT20210718051920N2**

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)

Phone

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Email address

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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 tea 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 tea 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

- Participant
- Investigator
- Outcome assessor
- Data analyser

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

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Province

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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 1: patients will receive a puff of the nasal spray containing tea tree oil two times per day for 14 days.

Category

Treatment - Drugs

2**Description**

Intervention group 2: patients will receive a puff of the placebo nasal spray, which is similar to the tea tree oil spray in shape, size, and color but contains 0.9% sodium chloride, two times per day for 14 days.

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Ear nose and throat clinic

Full name of responsible person

Aliasghar Arabi Mianroodi

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2**Recruitment center****Name of recruitment center**

Asthma and allergy clinic

Full name of responsible person

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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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Grant name**Grant code / Reference number**

400000100

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

Yes

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**

Kerman University of Medical Sciences

Full name of responsible person

Hamid Forootanfar

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Pharmaceutical Biotechnology

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

Naemeh Nikvarz

Position

Assistant professor

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Specialist

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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

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