

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jun 2026

Assessment of Origanum Vulgaris L. Effect on Allergic Rhinitis Compared to Placebo: a randomized-controlled clinical trial.

Protocol summary

Summary

Aims: assessment of Origanum Vulgaris L. Effect on Allergic Rhinitis Compared to Placebo. Study design: the study is blocked randomized, placebo controlled, double blind, uni-center clinical trial. Major inclusion criteria: men and women aged 18 to 60 years old; outpatients with a history or diagnosis of allergic rhinitis for at least 6 months before the first visit; allergic rhinitis and the numbers of eosinophil in the nasal mucous or the skin Prick test is proven (if not already done during the last 6 months); signing informed consent. Major exclusion criteria: patients taking drugs other than drugs that must consume according to the research plan, the duration of the project will be excluded from use; patients during the study have a fungal, viral or bacterial disease; patients who do not follow the recommended instructions. Sample size: 110 persons. Intervention duration: 14 months. Primary outcome or studied outcomes: effect of Origanum Vulgaris L. Effect on Allergic Rhinitis Compared to Placebo.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016061416925N2**
Registration date: **2016-10-26, 1395/08/05**
Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2016-10-26, 1395/08/05

Registrant information

Name

Seyed Morteza Emami Alorizi

Name of organization / entity

Shiraz University of Medical Sciences

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Iran (Islamic Republic of)

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+98 71 3230 5410

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smemami@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Sciences

Expected recruitment start date

2016-11-01, 1395/08/11

Expected recruitment end date

2017-03-01, 1395/12/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessment of Origanum Vulgaris L. Effect on Allergic Rhinitis Compared to Placebo: a randomized-controlled clinical trial.

Public title

Effect of Origanum Vulgaris L. on Allergic Rhinitis.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: men and women aged 18 to 60 years old; outpatients with a history or diagnosis of allergic rhinitis for at least 6 months before the first visit; allergic rhinitis and the numbers of eosinophil in the nasal mucous or the skin Prick test is proven (if not already done during the last 6 months); signing informed consent; patients with a diagnosis of allergic rhinitis are previous topical or systemic treatments include

antihistamines and corticosteroids have not responded or those with complications who have had previous with these drugs, do not want or cannot be treated with these drugs are; no anatomical abnormalities in the nose (nasal polyp or severe deviation); drugs that are used to treat allergies and if they use, it must be discontinued before the study; patients who are able to read and understand the consent form; ; patients who have not dementia; are not pregnant or are able to communicate and patients without nasopharyngeal tumors; patients who have not a history of drug allergy with Origanum vulgare. Exclusion criteria: patients taking drugs other than drugs that must consume according to the research plan, the duration of the project will be excluded from use; patients during the study have a fungal, viral or bacterial disease; patients who do not follow the recommended instructions will be excluded.

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **110**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shiraz University of Medcal Sciences

Street address

Shiraz University of Medcal Sciences(Central Building), Zand Ave.

City

Shiraz

Postal code

713451978

Approval date

2016-08-07, 1395/05/17

Ethics committee reference number

IR.SUMS.REC.1395.92

Health conditions studied

1

Description of health condition studied

Allergic Rhinitis

ICD-10 code

J30-J39

ICD-10 code description

Other diseases of upper respiratory tract

Primary outcomes

1

Description

The overall clinical symptoms.

Timepoint

Before the intervention and after intervention once a week, for a month.

Method of measurement

Rhinitis Quality of Life Questionnaire.

2

Description

Severity of rhinorrhea.

Timepoint

Before the intervention and after intervention once a week, for a month.

Method of measurement

Rhinitis Quality of Life Questionnaire.

3

Description

Severity of itchy nose.

Timepoint

Before the intervention and after intervention once a week, for a month.

Method of measurement

Rhinitis Quality of Life Questionnaire.

4

Description

Severity of nasal obstruction.

Timepoint

Before the intervention and after intervention once a week, for a month.

Method of measurement

Rhinitis Quality of Life Questionnaire.

5

Description

Frequency of sneezing per day.

Timepoint

Before the intervention and after intervention once a week, for a month.

Method of measurement

Rhinitis Quality of Life Questionnaire.

6

Description

Severity of itchy palate.

Timepoint

Before the intervention and after intervention once a week, for a month.

Method of measurement

Rhinitis Quality of Life Questionnaire.

7

Description

Severity of eye symptoms.

Timepoint

Before the intervention and after intervention once a week, for a month.

Method of measurement

Rhinitis Quality of Life Questionnaire.

8

Description

Number of nose palate eosinophils.

Timepoint

Before the intervention and after intervention once a week, for a month.

Method of measurement

Rhinitis Quality of Life Questionnaire.

Secondary outcomes

1

Description

Assessment of allergic rhinitis symptoms recovery based on the international diagnostic criteria of rhinitis quality of life questionnaire.

Timepoint

Before the intervention and after intervention once a week, for a month.

Method of measurement

Questionnaire.

Intervention groups

1

Description

Intervention group uses Origanum Vulgaris L. Extract; nasal spray, 40g/20ml, 2 puff, 3 times/day, for 1 month.

Category

Treatment - Drugs

2

Description

Control group uses placebo for 1 month.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Reza Polyclinic

Full name of responsible person

Seyed Morteza Emami Alorizi

Street address

Namazi square, Zand Ave., Shiraz, Fars, Iran.

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Seyed Basir Hashemi

Street address

Shiraz University of Medical Sciences, Zand Ave., Shiraz, Fars, Iran.

City

Shiraz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shiraz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Seyed Morteza Emami Alorizi

Position

PhD of PersianTraditional Medicine/The second presenter.

Other areas of specialty/work

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Position

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty