

# 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

###### Country

Iran (Islamic Republic of)

###### Phone

+98 71 3230 5410

###### Email address

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**

##### **Street address**

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## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Allergy Research Center.

**Full name of responsible person**

Seyed Hesamedin Nabavizade

**Position**

Professor

**Other areas of specialty/work**

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## Person responsible for updating data

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**Full name of responsible person**

Seyed Morteza Emami Alorizi

**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*