

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Assessment of the effect of Zofa (*Nepeta bracteata* Benth) Syrup on allergic rhinitis symptoms

Protocol summary

Summary

This is a double blind study, for Assessing the effect of Zofa (Hyssop)syrup and placebo on the treatment of allergic rhinitis. Qualified patients that fulfilled for inclusion criteria such as aged 18-65, not administered usual medicine in last two weeks, not lactation and pregnant, not having excluded criteria are entered and the patients with severe nose septal deviation, recent trauma to nose, lactating, pregnant females are excluded. The patients affected with allergic rhinitis were conducted to the study. The sample size in each group is 33 (case and control) The dose of zofa (Nepeta) syrup and placebo syrup is three times per day and each time 10cc. The patients diagnosed , confirmed by history and clinical examination and referred for allergic rhinitis disease by ENT specialist . The patients are randomly divided to two groups of placebo and intervention. Before entering in to study the required information is taken by the project agent, after receiving a written signed consent form and demographic questionnaire, standard questionnaire of ARIA, valid and reliable Persian questionnaire of allergic rhinitis are filled before and four weeks after prevention, the symptoms include : Sneezing, nasal obstruction, rhinorrhea, nose itching, eye symptoms (Redness, itching, watery), VAS (Visual analogue scale) are checked, then follow the necessary matters. At the end of the relevant information is extracted and analysed.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013122615943N1**
Registration date: **2015-02-04, 1393/11/15**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-02-04, 1393/11/15

Registrant information

Name

Mohammad reza haji heydari

Name of organization / entity

Shahed university

Country

Iran (Islamic Republic of)

Phone

+98 31 3364 1107

Email address

m.hajiheydari@med.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Shahed University of Medical Sciences

Expected recruitment start date

2014-12-01, 1393/09/10

Expected recruitment end date

2016-01-20, 1394/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessment of the effect of Zofa (*Nepeta bracteata* Benth) Syrup on allergic rhinitis symptoms

Public title

The effect of Zofa (*Nepeta bracteata* Benth) syrup on the allergic rhinitis disease

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Male and female patients aged 18 to 65 years with symptoms of allergic rhinitis; not taking of medicine commonly used allergic rhinitis for at least two weeks prior to admission; having of seasonal allergic rhinitis and perennial (intermittent and continuous); having criteria for allergic rhinitis based on the ARIA questionnaire; affected to mild allergic rhinitis. Exclusion criteria: Chronic diseases such as asthma, cancer; taking any medication known to affect chemical and herbal on allergic rhinitis; recent trauma to the nose; recent surgery of the nose; people exposed to irritants; pregnancy and lactation; the risk of epilepsy; vasomotor rhinitis; alpha-blocker drugs administration; the symptoms of acute sinusitis; taking systemic immunosuppressive therapy.

Age

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

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **66**

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

Shahed University ethics committee

Street address

Shahed University, apposite to Imam Khomeini Holly Shrine, Khalij Fars free way

City

Tehran

Postal code

Approval date

2014-11-22, 1393/09/01

Ethics committee reference number

41/215591

Health conditions studied

1

Description of health condition studied

Allergic rhinitis

ICD-10 code

J30.2

ICD-10 code description

Other seasonal allergic rhinitis

2

Description of health condition studied

Other allergic rhinitis

ICD-10 code

J30.3

ICD-10 code description

Other allergic rhinitis

Primary outcomes

1

Description

Sneezing

Timepoint

Before and four weeks after intervention

Method of measurement

ARIA Questionnaire And VAS

2

Description

Nasal obstruction

Timepoint

Before and four weeks after intervention

Method of measurement

ARIA Questionnaire And VAS

3

Description

Rhinorrhea

Timepoint

Before and four weeks after intervention

Method of measurement

ARIA Questionnaire And VAS

4

Description

Watery ,itchy ,red eyes

Timepoint

Before and four weeks after intervention

Method of measurement

ARIA Questionnaire And VAS

5

Description

Itchy nose

Timepoint

Before and four weeks after intervention

Method of measurement

Secondary outcomes

empty

Intervention groups

1

Description

Zofa (Hyssop) syrup, three times a day, each time 10 cc for four weeks

Category

Treatment - Drugs

2

Description

Placebo syrup, three times a day each time 10 cc for four weeks

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Mostafa Khomeini hospital

Full name of responsible person

Mohammad Ebrahim Yarmohammadi, MD

Street address

Italia street

City

Tehran

2

Recruitment center

Name of recruitment center

Iranian traditional medicine clinic of Shahed university

Full name of responsible person

Mohammad Reza Haji heydari

Street address

Beside of Arman dead lock ,third Dashtestan alley, Shariati street

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

shahed University of Medical Sciences

Full name of responsible person

Mohsen Naseri.MD

Street address

Traditional Medicine Clinical Trial Research Center:
No.1471 : Between Forsat and Nosrat Ave: North
Kargar Ave: Enghelab Ave.

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

shahed 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

Shahed University of Medical Sciences

Full name of responsible person

Mohammad Reza Haji heydari

Position

Resident ph.D of Iranian Traditional Medicine

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Mohammad Ebrahim Yarmohammadi. MD

Position

ENT Specialist

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity
Shahed University of Medical Sciences
Full name of responsible person
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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