

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 2026

Effect of Maa-al-shaeer (An Iranian Traditional Medicine product) on treatment of allergic rhinitis in comparison with fexofenadine

Protocol summary

2016-01-25, 1394/11/05

Summary

Purpose of the study: Evaluation of the effect of Maa-al-shaeer (An Iranian Traditional Medicine product) on treatment of allergic rhinitis in comparison with Fexofenadine. In this study 80 patients with allergic rhinitis (according to ARIA guideline) that were referred to Baqiyatallah Hospital Clinic or Traditional Medicine Clinic of Shahid Beheshti University of Medical Sciences, are enrolled in the study and randomly divided into two groups of 40 (A & B). Patients who have received Corticosteroid within past two weeks or patients who have received antihistamines within the past one week before the beginning of the study or those who suffering from other systemic or autoimmune disorders are not enrolled in the study. Group A will receive Maa-al-Sheer (15 gram of powder in 250 cc lukewarm water twice daily) and group B will receive Fexofenadine (60 mg tablet twice daily) for a period of two weeks. Clinical symptoms (using JTFPP questionnaire) and paraclinical parameters (including blood eosinophil count, Ig-E, IFN-gamma, TGF-beta, IL-4, IL-17) will be evaluated and documented in the beginning and at the end of second week. After that the patients are advised not to use any medicine for one week. The symptom aggravation will be checked at the end of third week following one week of withdrawal of the drug (using RCAT questionnaire)

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015082323732N1**
Registration date: **2016-01-25, 1394/11/05**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

Registrant information

Name

Alireza Derakhshan

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3884 8931

Email address

ar.derakhshan@sbm.ac.ir

Recruitment status

Recruitment complete

Funding source

Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2015-10-07, 1394/07/15

Expected recruitment end date

2017-02-19, 1395/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Maa-al-shaeer (An Iranian Traditional Medicine product) on treatment of allergic rhinitis in comparison with fexofenadine

Public title

Effect of Maa-al-shaeer (An Iranian Traditional Medicine product) on treatment of allergic rhinitis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: All patients 7 years to 65 years old that according to the ARIA guideline and diagnosis of a

pulmonologist have allergic rhinitis a Exclusion criteria: Diffused Nasal Polyps; Pregnancy; history of allergy to Fexofenadine or barley; Celiac disease; systemic inflammatory diseases; using antihistamines during the last week before the beginning of the study; using Corticosteroids during the last 2 weeks before the beginning of the study; Using other antihistamine drugs during the study; using corticosteroid drugs during the study; Lack of consent from the patient to stay in the study for any reason; drug intolerance or allergic reactions

Age

From **7 years** old to **65 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shahid Beheshti University of Medical Sciences Ethics Committee

Street address

7th Floor , 2nd SBUMS Bldg. ,Next to Ayatollah Taleghani Hospital, Evin , Tehran, Iran.

City

Tehran

Postal code

1985717443

Approval date

2015-09-27, 1394/07/05

Ethics committee reference number

IR.SBMU.RAM.REC.1394.237

Health conditions studied

1

Description of health condition studied

Allergic Rhinitis

ICD-10 code

J30.4

ICD-10 code description

Allergic rhinitis, unspecified

Primary outcomes

1

Description

Clinical symptoms

Timepoint

Baseline and 2 weeks after intervention

Method of measurement

JTFPP questionnaire and based on VAS

2

Description

IFN-gamma

Timepoint

Baseline and 2 weeks after intervention

Method of measurement

Blood sample and measurement using RT-PCR

3

Description

IL-4

Timepoint

Baseline and 2 weeks after intervention

Method of measurement

Blood sample and measurement using RT-PCR

4

Description

IL-17

Timepoint

Baseline and 2 weeks after intervention

Method of measurement

Blood sample and measurement using RT-PCR

5

Description

TGF-beta

Timepoint

Baseline and 2 weeks after intervention

Method of measurement

Blood sample and measurement using RT-PCR

6

Description

Ig-E levels

Timepoint

Baseline and 2 weeks after intervention

Method of measurement

Blood sample / IU/ml

7

Description

Blood Eosinophil level

Timepoint

Baseline and 2 weeks after intervention

Method of measurement

Blood sample / IU/ml

8

Description

nasal smear eosinophil count

Timepoint

Baseline and 2 weeks after intervention

Method of measurement

eosinophil count in nasal smear

Secondary outcomes

1

Description

symptom recurrence rate

Timepoint

Baseline and one week after the end of intervention

Method of measurement

RCAT questionnaire

2

Description

Levels of AST, ALT, BUN, Cr in the group taking the Ma-al-Shaeer to evaluate its effect on hepatic and renal function

Timepoint

Baseline and two weeks after intervention

Method of measurement

blood samples

Intervention groups

1

Description

Intervention group: Receiving 15mg of Maa-al-shaeer powder in 250cc water, twice a day for 2 weeks

Category

Treatment - Drugs

2

Description

Control Group: Receiving Fexofenadine tablets 60mg twice a day for 2 weeks

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Traditional Medicine Clinic of Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr.Alireza Derakhshan

Street address

No.8 Shams Alley, Vali-e-Asr Street

City

Tehran

2

Recruitment center

Name of recruitment center

Baqiyatallah Hospital Clinic

Full name of responsible person

Dr.Mostafa Ghanei

Street address

Baqiyatallah Hospital, Mollasadra Street

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr Mahmood Mosadegh

Street address

No.8 Shams Alley, Opposite of Tavanir St, Vali Asr St, Tehran

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research, Shahid Beheshti 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

School of Traditional Medicine, Shahid Beheshti
University of Medical Sciences

Full name of responsible person

Dr Alireza Derakhshan

Position

PhD student of Iranian Traditional Medicine

Other areas of specialty/work**Street address**

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Person responsible for scientific inquiries

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Full name of responsible person

Dr Mahmood Khodadoost

Position

Associate Professor

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Full name of responsible person

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Position

Ph.D student of Iranian Traditional Medicine

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Web page address

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