Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

The effect of sweet pomegranate juice on the severity of symptoms in patients with allergic rhinitis: A double-blinded, randomized clinical trial

Protocol summary

Study aim
Determining the effect of pomegranate juice on the severity of symptoms in patients with allergic rhinitis

Design
A randomized superiority double blinded clinical trial. n=60, randomization will be conducted with blocking method through www.randomization.com

Settings and conduct
This clinical trial will be conducted in the Allergy, Ear, Nose, and Throat Clinic of Imam Reza and Qaim Hospital as a randomized, double-blind clinical trial. Patients with allergic rhinitis who visit the hospital clinic as an outpatient will be evaluated individually by a doctor. The patients who meet the conditions to enter the study are included and assigned to intervention and control groups using a simple randomization method. After obtaining the patient's consent (complete explanation of the plan), their approval is obtained. The severity of the disease in these patients will be evaluated at the beginning of the project by interviewing the doctor and using the standard Sino-Nasal Test 20 questionnaire. The result will be recorded in the questionnaire for each patient.

Participants/Inclusion and exclusion criteria
Allergic rhinitis patients People aged 18 to 60 years Exclusion criteria: Pregnancy or breastfeeding non-allergic rhinitis systemic diseases Taking herbal supplements with antioxidant properties Liver dysfunction Kidney dysfunction Thyroid disorders Epilepsy

Intervention groups
In the intervention group, patients will receive sweet pomegranate juice concentrate (ml/day 50) and antihistamine and corticosteroid drugs and in the control group, patients will receive antihistamine and corticosteroid drugs for 2 months.

Main outcome variables
Determining the severity of clinical symptoms of patients using the SNOT-20 questionnaire, Salsola-specific IgE , Th1/Th2 cytokines, interferon (IFN)-γ, and interleukin IL-4 and IL-5 concentrations before the intervention and at the end of the study

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20221012056153N1**
Registration date: **2023-03-16, 1401/12/25**
Registration timing: **retrospective**

Last update: **2023-03-16, 1401/12/25**
Update count: **0**

Registration date
2023-03-16, 1401/12/25

Registrant information

Name
Maryam Akaberi

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-12-22, 1401/10/01

Expected recruitment end date
2023-01-21, 1401/11/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of sweet pomegranate juice on the severity of symptoms in patients with allergic rhinitis: A double-blinded, randomized clinical trial

Public title
The effect of pomegranate juice on allergic rhinitis

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Allergic rhinitis patients Patients who have been treated with standard drugs including antihistamines and corticosteroids for at least 4 weeks and have had a poor or no response to these treatments are included in the study.

Exclusion criteria:
Pregnancy or breastfeeding Patients with non-allergic rhinitis Patients with systemic diseases Use of herbal supplements with antioxidant properties Liver dysfunction (LFT>3ULN) Kidney dysfunction (GFR<60 ml/kg/min) Thyroid disorders (based on thyroid function test) Epilepsy

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

Gender
Both

Phase
N/A

Groups that have been masked

- Care provider
- Data analyser

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
The size of each block will be 4. Then write the list of blocks and assign numbers to them, for example (AABB(1)- BBAA(2)- BABA(3)- BAAB(4)), which will be 8 blocks according to the sample size of 30 people. Then the selection of random numbers according to the site WWW.randomization.com and finally the prepared blocks will be placed in the envelope. According to the order of arrival of patients, one of the envelopes will be randomly selected and patients will be assigned to groups based on the obtained blocks.

Blinding (investigator's opinion)
Double blinded

Blinding description
Due to the non-use of placebo in the control group, only the therapists will not be informed about the assigned treatment, and the analyst will also be unaware of the assigned treatment to the two groups. Finally, after analyzing the data, the researcher who prepared the packages reveals the code A and B.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Mashhad University of Medical Sciences

Street address
Vakilabad Blvd.

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Mashhad

Province
Razavi Khorasan

Postal code
9177948954

Approval date
2022-05-10, 1401/02/20

Ethics committee reference number
IR.MUMS.MEDICAL.REC.1401.121

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
Determining the severity of clinical symptoms of patients (including sneezing, an itchy nose, a runny or blocked nose, itchy, red and watery eyes, a cough, the roof of mouth being itchy)

Timepoint
Beginning and end of the study (zero and 60 days)

Method of measurement
Using of Sino-Nasal Test 20 (SNOT-20)

Secondary outcomes

1

Description
The level of specific IgE

Timepoint

Beginning and end of the study (zero and 60 days)

Method of measurement

Collection of blood samples from patients

2

Description

Th1/Th2 cytokines

Timepoint

Beginning and end of the study (zero and 60 days)

Method of measurement

Collection of blood samples from patients

3

Description

Determination of interferon (IFN)-γ concentration

Timepoint

Beginning and end of the study (zero and 60 days)

Method of measurement

Collection of blood samples from patients

4

Description

Determination of interleukin IL-4 and IL-5 concentrations

Timepoint

Beginning and end of the study (zero and 60 days)

Method of measurement

Collection of blood samples from patients

Intervention groups

1

Description

Intervention group: Patients will receive sweet pomegranate juice concentrate (ml/day 50) for 2 months, in addition to taking antihistamine and corticosteroid drugs. Pomegranate concentrate refers to concentrated pomegranate juice. The concentrate is purchased from one of the concentrate production companies (Narni, Tehran, Website: https://narni.ir/). Then the concentrate is divided into syrup jars and kept in the freezer until use.

Category

Treatment - Drugs

2

Description

Control group: In the control group, patients will receive antihistamine and corticosteroid drugs for 8 weeks

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Allergy, ear, throat and nose clinic of Imam Reza and Qaim Hospital

Full name of responsible person

Dr Mahdi Bakhshaee

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Sponsors / Funding sources

1

Sponsor

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Grant name

Mashhad University of Medical Sciences (4000758)

Grant code / Reference number

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

Yes

Title of funding source

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person
Dr Mahdi Bakhshaee

Position
Professor

Latest degree
Subspecialist

Other areas of specialty/work
Ear, Nose, and Throat

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Person responsible for scientific inquiries

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Assistant Professor

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Specialist

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PhD Student

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
Part of the data, such as information related to the main outcome or similar, can be shared

When the data will become available and for how long
The access period begins 6 months after the publication of the results

To whom data/document is available
Researchers working in academic and scientific institutions or people who are also working in the industry can apply for them.

Under which criteria data/document could be used
Drug discovery

From where data/document is obtainable
Corresponding researcher

What processes are involved for a request to access data/document
one week

Comments