

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Evaluating the effect of pomegranate extract on some serum immunologic factors(IL-35, hs-CRP), oxidative stress status (PAB) and spirometry test in patients with persistent allergic asthma with mild and moderate severity

Protocol summary

Study aim

In this study, the effect of pomegranate extract on asthma will be examined.

Design

A clinical trial with control group including a sample size of 64 people, with parallel group, double-blind, randomized

Settings and conduct

This study is a randomized, double-blind, placebo-controlled trial, which the researcher and participants will be blinded by encoding pomegranate extract and placebo by the other person. The subjects are patients with asthma who will be selected from the pulmonary department of Imam Khomeini hospital in Ahvaz, which will have the inclusion criteria to enter the study. The participants will be randomized through the statistical method of permuted block. Blocks will be determined using statistical software.

Participants/Inclusion and exclusion criteria

Ages 18 to 65 years, Mild to moderate persistent allergic asthma, Body mass index: 18.5-30

Intervention groups

2 groups: one group will receive supplement of pomegranate extract and the other group will be presented placebo (toasted flour).

Main outcome variables

prooxidant-antioxidant balance

General information

Reason for update

Due to the rising dollar and increasing prices of kits, we had to remove a series of parameters in the study, which in turn will change the title and a series of goals in the research design.

Acronym

IRCT registration information

IRCT registration number: **IRCT20200205046384N1**

Registration date: **2020-05-09, 1399/02/20**

Registration timing: **registered_while_recruiting**

Last update: **2021-03-01, 1399/12/11**

Update count: **1**

Registration date

2020-05-09, 1399/02/20

Registrant information

Name

Zainab Shateri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3373 8330

Email address

shateri.z@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-04-20, 1399/02/01

Expected recruitment end date

2020-11-20, 1399/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the effect of pomegranate extract on some

serum immunologic factors(IL-35, hs-CRP), oxidative stress status (PAB) and spirometry test in patients with persistent allergic asthma with mild and moderate severity

Public title

investigating the effect of pomegranate extract in asthma

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Ages 18 to 65 years Patients with mild to moderate persistent allergic asthma, Forced Expiratory Volume in First Second(FEV1) greater than 60% Body mass index(BMI):18.5-30 Both sexes

Exclusion criteria:

smoking Diabetes Pregnancy and lactation Autoimmune diseases Malignancies Digestive, liver or kidney problems Pneumonia Other pulmonary diseases Antioxidant usage blood pressure-lowering drugs (Statin and ACE Inhibitors)

Age

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

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **64**

Randomization (investigator's opinion)

Randomized

Randomization description

The participants will be randomized through the statistical method of permuted block. Blocks will be determined using statistical software.

Blinding (investigator's opinion)

Double blinded

Blinding description

The researcher and participants are blinded by coding the drug in the form of A and B, so that someone else is asked to encode the pomegranate extracts and placebo to A and B which are similar in appearance. The participants and the researcher will be uninformed of the type of intervention. As a result, the study will be performed in the forms of double blind.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committee of Ahvaz Jondishapour University of Medical Sciences

Street address

Nutrition dep, faculty of Paramedicine, Ahvaz Jondishapour University of Medical Sciences, Golestan Highway, Ahvaz Town

City

Ahvaz

Province

Khouzestan

Postal code

6135715794

Approval date

2020-02-21, 1398/12/02

Ethics committee reference number

IR.AJUMS.REC.1398.905

Health conditions studied

1

Description of health condition studied

Asthma

ICD-10 code

J45.0

ICD-10 code description

آسم

Primary outcomes

1

Description

prooxidant-antioxidant balance

Timepoint

at the beginning of the study and 8 weeks after the intervention

Method of measurement

Based on blood test using calorimetry

2

Description

Forced Vital Capacity(FVC)/Forced Expiratory Volume in First Second(FEV1), FEV1, FVC

Timepoint

at the beginning of the study and 8 weeks after the intervention

Method of measurement

Based on the result of the spirometer- Variable scale: percent

Secondary outcomes

1

Description

High sensitivity C-reactive protein (hsCRP)

Timepoint

At the beginning of the study and 8 weeks after intervention

Method of measurement

Laboratory measurement (quantitative luminescence) - mg / dl

2

Description

blood pressure

Timepoint

At the beginning of the study and 8 weeks after the intervention

Method of measurement

Based on the results of the Easy Life aneroid Sphygmomanometer-mmHg

3

Description

Clinical variables and general patient status

Timepoint

At the beginning of the study and 8 weeks after the intervention

Method of measurement

Based on a questionnaire filled by a specialist physician

4

Description

IL-35

Timepoint

At the beginning of the study and 8 weeks after the intervention

Method of measurement

Based on laboratory measurements-pg/ml

5

Description

complete blood cell count and differential count

Timepoint

At the beginning of the study and 8 weeks after the intervention

Method of measurement

Based on laboratory measurement

Intervention groups

1

Description

Intervention group: group receiving pomegranate extract 500 mg / day in capsule form (two 250 mg capsules daily). Drug production center: The institute of medicinal plants research of Jahad Daneshgahi. The duration of drug use is 8 weeks.

Category

Treatment - Drugs

2

Description

Control group: Placebo-receiving group: Two capsules daily containing 250 mg toasted flour . Drug Production Center: The institute of medicinal plants research of Jahad Daneshgahi. The duration of drug use is 8 weeks.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Ahvaz Imam Khomeini hospital

Full name of responsible person

Maryam Haddadzadeh Shoushtari. Lung specialist

Street address

Imam Khomeini hospital, 24 metry Ave, Ahvaz

City

Ahvaz

Province

Khouzestan

Postal code

00986135715794

Phone

+98 61 3336 7543

Fax

+98 61 3336 1544

Email

shateri.z@ajums.ac.ir

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Dr. Mohammad Badavi

Street address

Development Unit, Ahvaz Jundishapur University of Medical Sciences, Golestan Boulevard, Ahvaz

City

Ahvaz

Province

Khouzestan

Postal code

00986135715794

Phone

+98 61 3336 2414

Fax

+98 61 3336 1544

Email

itc@ajums.ac.ir

Web page address

Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Ahvaz 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
Ahvaz University of Medical Sciences
Full name of responsible person
Zainab Shateri
Position
PhD student
Latest degree
Ph.D.
Other areas of specialty/work
Nutrition
Street address
Nutrition Department, Faculty of Paramedicine, Ahvaz Jondishapour University of Medical Sciences, Golestan Blvd
City
Ahvaz
Province
Khouzestan
Postal code
6135715794
Phone
0098613311
Email
shateri.z@ajums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Zainab Shateri
Position
PhD student
Latest degree
Ph.D.
Other areas of specialty/work
Nutrition

Street address
Department of Nutrition, Faculty of Paramedicine, Ahvaz Jundishapur University of Medical Sciences, Golestan Blvd
City
Ahvaz
Province
Khouzestan
Postal code
6137515794
Phone
0098613311
Email
shateri.z@ajums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Zainab Shateri
Position
PhD student
Latest degree
Ph.D.
Other areas of specialty/work
Nutrition
Street address
Department of Nutrition, Faculty of Paramedicine, Ahvaz Jondishapour University of Medical Sciences, Golestan Blvd
City
Ahvaz
Province
Khouzestan
Postal code
6135715794
Phone
0098613311
Email
shateri.z@ajums.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No more information.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available