Clinical Trial Protocol
Iranian Registry of Clinical Trials

23 Nov 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 received 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

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Iran (Islamic Republic of)

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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
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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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
Dr. Mohammad Badavi
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Development Unit, Ahvaz Jundishapur University of Medical Sciences, Golestan Boulevard, Ahvaz
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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
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Person responsible for updating data

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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