Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Investigation of the effect of saffron supplementation on the some immunologic factors and oxidative Stress in patients with moderate persistent allergic asthma

Protocol summary

Study aim

Determination of the effect of saffron supplementation on some immunologic factors and oxidative stress in patients with moderate persistent allergic asthma.

Design

An 8 weeks' double blind randomized placebo-controlled clinical trial with parallel groups.

Settings and conduct

Persons referring to the Imam Khomeini Hospital in Ahvaz who are diagnosed as having a moderate severity of allergic asthma that diagnosed by a physician and have inclusion criteria will be randomly divided into saffron and the placebo group. Blood samples will be collected for the evaluation of Interleukin 10 (IL-10), Transforming growth factor β (TGF-β), Interleukin 35 (IL-35), Prooxidant-antioxidant Balance (PAB) and Complete Blood Count-differential (CBC-diff) at the beginning and after 8 weeks of intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: age between 18 to 65 years old; moderate persistent allergic asthma according to the physician diagnosis and normal body mass index (up to 27). Inclusion criteria dos not belong to the particular gender and includes both of male and female. Non-entry criteria: smoking; diabetes; pregnancy and lactation; autoimmune disease; malignancies; gastrointestinal, liver and kidney disease; pneumonia and other pulmonary disease; taking antioxidant supplements and unwilling to continue the study.

Intervention groups

Individuals will be randomly divided into two groups of 38 patients receiving 100 mg of saffron per day and 38 patients receiving 100 mg of starch (placebo) per day for 8 weeks.

Main outcome variables

Interleukin 10 (IL-10), Transforming growth factor β (TGF-β), Interleukin 35 (IL-35) and Prooxidant-antioxidant Balance (PAB)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180418039354N1**
Registration date: **2018-06-02, 1397/03/12**
Registration timing: **prospective**

Last update: **2018-06-02, 1397/03/12**
Update count: **0**

Registration date

2018-06-02, 1397/03/12

Registrant information

Name

mehdi bahreini

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-06-05, 1397/03/15

Expected recruitment end date

2018-08-06, 1397/05/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Investigation of the effect of saffron supplementation on the some immunologic factors and oxidative Stress in patients with moderate persistent allergic asthma

Public title
Investigation of the effect of saffron on asthma

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age between 18 to 65 years old Moderate persistent allergic asthma according to the physician Normal body mass index (up to 27)

Exclusion criteria:
Smoking Diabetes Pregnancy and lactation Autoimmune disease, malignancies, gastrointestinal, liver and kidney disease, pneumonia and other pulmonary disease Taking antioxidant supplements Unwilling to continue the study

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

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **76**

Randomization (investigator's opinion)
Randomized

Randomization description
Block Randomization will be used to divide the patients into the intervention or placebo groups. According to the sample size and having intervention and control groups, 6 blocks will be used to divide the patients into 2 groups. Possible forms for classifying into the A or B will be written in 6 blocks. The entry of individuals into each of the A or B groups will be done by using the obtained number of blocks from the random table and the layout in the block.

Blinding (investigator's opinion)
Double blinded

Blinding description
Patients will receive the 2 capsule that completely identical in shape, size and color. These capsules are prepared by a person who does not involve in the protocol of this study. None of the people involved in the study and the participants not will be aware of the A or B capsules content.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Ahvaz Jundishapur University of Medical Sciences

Street address
Ahvaz Jundishapur University of Medical Sciences, Golestan Highway, Ahvaz, Iran

City
Ahvaz

Province
Khouzestan

Postal code
00986135715794

Approval date
2018-03-09, 1396/12/18

Ethics committee reference number
IR.AJUMS.REC.1396.1095

Health conditions studied

1

Description of health condition studied
Moderate persistent allergic asthma

ICD-10 code
J45.4

ICD-10 code description
Moderate persistent allergic asthma

Primary outcomes

1

Description
Interleukin 10 (IL-10)

Timepoint
The beginning and end of supplementation

Method of measurement
ELISA method

2

Description
Transforming growth factor β (TGF-β)

Timepoint
The beginning and end of supplementation

Method of measurement
ELISA method

3

Description
Interleukin 35 (IL-35)

Timepoint

The beginning and end of supplementation

Method of measurement

ELISA method

4

Description

Prooxidant-antioxidant Balance (PAB)

Timepoint

The beginning and end of supplementation

Method of measurement

ELISA method

Secondary outcomes

1

Description

Complete Blood Count-differential (CBC-diff)

Timepoint

The beginning and end of the supplementation

Method of measurement

Will be assessed by Sysmex device

2

Description

A frequency of shortness of breath in the day or night

Timepoint

The beginning and end of the supplementation

Method of measurement

Based on the patient's response (number per week)

3

Description

How often do you wake up because of asthma symptoms

Timepoint

The beginning and end of the supplementation

Method of measurement

Based on the patient's response (number per week)

4

Description

Frequency of activity limitation due to asthma and shortness of breath

Timepoint

The beginning and end of the supplementation

Method of measurement

Based on the patient's response (number per week)

5

Description

The frequency of use of salbutamol spray

Timepoint

The beginning and end of the supplementation

Method of measurement

Based on the patient's response (number per week)

Intervention groups

1

Description

Intervention group: consumption 100 mg of saffron (capsule) per day (two 50 mg capsule per day)

Category

Treatment - Drugs

2

Description

Control group: consumption two capsules containing starch per day

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital

Full name of responsible person

Maryam Haddadzadeh

Street address

Imam Khomeini Hospital, 24 meters St, Ahvaz, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Mohammad Badvi

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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
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available