

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jun 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)

Phone

+98 61 3373 8499

Email address

bahreini.m@ajums.ac.ir

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

City

Ahvaz

Province

Khuzestan

Postal code

00986135715784

Phone

+98 61 3373 8499

Email

Bahreini.m@ajums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Mohammad Badvi

Street address

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

City

Avaz

Province

Khuzestan

Postal code

00986135715794

Phone

+98 61 3336 7543

Email

Bahreini.m@ajums.ac.ir

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
Mehdi Bahreini
Position
Ph.D student
Latest degree
Master
Other areas of specialty/work
Nutrition
Street address
Ahvaz Jundishapur University of Medical Sciences,
Golestan Highway, Ahvaz, Iran
City
Ahvaz
Province
Khuzestan
Postal code
00986135715794
Phone
+98 61 3373 8499
Email
Bahreini.m@ajums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Mehdi Bahreini
Position
Ph.D student
Latest degree
Master
Other areas of specialty/work
Nutrition
Street address
Ahvaz Jundishapur University of Medical Sciences,

Golestan Highway, Ahvaz, Iran
City
Ahvaz
Province
Khuzestan
Postal code
00986135715794
Phone
+98 61 3373 8499
Email
Bahreini.m@ajums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Mehdi Bahreini
Position
Ph.D student
Latest degree
Master
Other areas of specialty/work
Nutrition
Street address
Ahvaz Jundishapur University of Medical Sciences,
Golestan Highway, Ahvaz, Iran
City
Ahvaz
Province
Khuzestan
Postal code
00986135715794
Phone
+98 61 3373 8499
Email
Bahreini.m@ajums.ac.ir

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