

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jun 2026

Survey the effect of saffron supplementation on the antibody titer to heat-shock protein (HSP) 70, hsCRP and spirometry test in patients with moderate persistent allergic asthma

Protocol summary

Summary

Objectives: determination the effect of saffron supplementation on the antibody titer to heat-shock protein (HSP) 70, hsCRP and spirometry test in patients with moderate persistent allergic asthma Design: the study population includes patients referred to the Red Crescent special clinic with diagnosed moderate persistent allergic asthma by doctors. Study groups include saffron and placebo consumer groups. Sample size includes 86 subjects. Study will be done in triple-blind, block randomized and single-center manner and phase 1 clinical trial. Setting and conduct: In this study patients with moderate persistent allergic asthma will randomly divided into saffron and placebo consumer groups and supplementation will be done for 8 weeks. Participants: Inclusion criteria include age between 18 to 65 years old, moderate persistent allergic asthma and normal BMI and exclusion criteria include smoking, diabetes, autoimmune disease, malignancies, gastrointestinal, liver and kidney disease, pneumonia, pregnancy and lactation and not wanting to continue cooperation. Intervention: include saffron capsule consumer and capsule consumer groups. Main outcome variables: Antibody titers to heat shock protein 70, FEV1, FVC, FEV1/FVC, hsCRP, blood pressure, lipid profile, clinical variables and the patient's general status.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017012132081N2**

Registration date: **2017-04-03, 1396/01/14**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2017-04-03, 1396/01/14

Registrant information

Name

Marzie Zilaei

Name of organization / entity

Department of Nutrition-paramedicine school

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Ahvaz jundishapur university of medical sciences

Expected recruitment start date

2017-04-20, 1396/01/31

Expected recruitment end date

2017-08-22, 1396/05/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Survey the effect of saffron supplementation on the antibody titer to heat-shock protein (HSP) 70, hsCRP and spirometry test in patients with moderate persistent allergic asthma

Public title

Survey the effect of saffron on asthma

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age between 18 to 65 years old, moderate persistent allergic asthma (FEV1 between 40 to 60 percent) according to the physician and normal BMI (up to 27). Inclusion criteria does not belong to the particular gender and include male and females. Exclusion criteria include smoking, diabetes, pregnancy and lactation, autoimmune disease, malignancies, gastrointestinal, liver and kidney disease, pneumonia and other pulmonary disease and Not wanting to continue cooperation

Age

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

Gender

Both

Phase

1

Groups that have been masked

No information

Sample size

Target sample size: **86**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Triple blinded

Blinding description

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. Golestan Bolvar. Jundishapur University of Medical Sciences. Research Assistance

City

Ahvaz

Postal code

Approval date

2017-03-07, 1395/12/17

Ethics committee reference number

IR.AJUMS.REC.1395.810

Health conditions studied

1

Description of health condition studied

moderate persistent allergic asthma

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Antibody titers to heat shock protein 70

Timepoint

Before and two months after intervention

Method of measurement

according to the Laboratory Measurement-ng/ml

2

Description

FEV1, FVC, FEV1/FVC

Timepoint

Before and two months after intervention

Method of measurement

According to the results of the spirometer-scale:percent

Secondary outcomes

1

Description

hsCRP

Timepoint

Before and two months after intervention

Method of measurement

according to the laboratory measurement-mg/dl

2

Description

lipid profile

Timepoint

Before and two months after intervention

Method of measurement

according to the laboratory measurement-mg/dl

3

Description

blood pressure

Timepoint

Before and two months after intervention

Method of measurement

according to the results of Sphygmomanometer-mmhg

4

Description

clinical variables and the patient's general status

Timepoint

Before and two months after intervention

Method of measurement

according to the Questionnaires completed by physician superspecialty

Intervention groups

1

Description

Saffron consumer group which receiving 100 mg of saffron per day in capsule form (two 50 mg capsule per day). Drug producing center: growth center of Ahvaz Jundishapur University of medical sciences. Duration of drug consumption is 8 weeks.

Category

Treatment - Drugs

2

Description

Placebo consumer group: consumption two capsules per day which containing starch. Drug producing center: growth center of Ahvaz Jundishapur University of medical sciences. Duration of drug consumption is 8 weeks.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Ajvaz Imam Khomeini hospital

Full name of responsible person

Maryam Haddadzadeh shushtari. Lung superspecialist

Street address

Ahvaz. 24 m street. Imam Khomeini hospital. Special clinic

City

Ahvaz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Dr Behzad Sharif Makhmalzadeh

Street address

Ahvaz-Golestan bolvar-Ahvaz jundishapur univesity of medical sciences-development unit

City

Ahvaz

Grant name

-

Grant code / Reference number

-

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

Yes

Title of funding source

Vice Chancellor for research of Ahvaz Jundishapur University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Department of nutrition, paramedicine school

Full name of responsible person

Marzie Zilae

Position

MSc.Ph.D student

Other areas of specialty/work

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty