

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jul 2026

Survey the effect of zinc gluconate supplementation on the serum levels of IL-35, oxidative stress, eosinophils and basophils status, spirometry test and clinical symptoms in patients with mild and moderate persistent allergic asthma.

Protocol summary

Registration timing: **prospective**

Study aim

Determination the effect of zinc gluconate supplementation on the serum levels of IL-35, C-reactive protein, oxidative stress status, spirometry test and clinical symptoms in patients with mild and moderate persistent allergic asthma.

Last update: **2022-11-02, 1401/08/11**

Update count: **0**

Registration date

2022-11-02, 1401/08/11

Design

A clinical trial with control group including a sample size of 62 people, with parallel group, double-blind, randomized

Registrant information

Name

Pardis Tofighzadeh

Name of organization / entity

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Iran (Islamic Republic of)

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Settings and conduct

Referred to the Ahvaz Asthma and Allergy Clinic in 2022, selection of 62 patients based on inclusion and exclusion criteria, randomization into intervention and control groups. Blinding of patients and researchers, coding by a third party who does not know the details.

Recruitment status

Recruitment complete

Funding source

Participants/Inclusion and exclusion criteria

Ages 18 to 65 years, Mild to moderate persistent allergic asthma, Body mass index: 18.5-30 kg/m²; Non-inclusion criteria: smoking, Pregnancy and lactation, Cardiovascular diseases and other chronic diseases, Use of antioxidant or zinc supplements in the last three months, Not wanting to continue cooperation

Expected recruitment start date

2022-11-22, 1401/09/01

Expected recruitment end date

2023-05-04, 1402/02/14

Intervention groups

Study groups include zinc gluconate and placebo consumer groups

Actual recruitment start date

empty

Actual recruitment end date

empty

Main outcome variables

IL-35; TAC; FEV₁, FVC, FEV₁/FVC

Trial completion date

empty

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220507054764N1**

Registration date: **2022-11-02, 1401/08/11**

Scientific title

Survey the effect of zinc gluconate supplementation on the serum levels of IL-35, oxidative stress, eosinophils and basophils status, spirometry test and clinical symptoms in patients with mild and moderate persistent

allergic asthma.

Public title

Survey the effect of zinc gluconate on asthma

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age 18 to 65 years Patients with mild to moderate persistent allergic asthma Body mass index(BMI):20-30 kg/m2 Both genders

Exclusion criteria:

smoking Pregnancy and lactation Cardiovascular diseases and other chronic diseases Use of antioxidant or zinc supplements in the last three months Not wanting to continue cooperation

Age

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

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **62**

Randomization (investigator's opinion)

Randomized

Randomization description

In this trial, random block method will be used to assign people to groups. In order to reduce the possibility of information bias, a double-blind method will be used. In this way, both the patients and researcher will be kept unaware of the type of treatment assigned to the patients. Also, in order to reduce the possibility of selection bias, Allocation Concealment method will be used after randomization and by using unit codes.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, the double-blind method will be used to reduce the possibility of information bias. In this way, both the patients and the researchers will be kept unaware of the type of treatment assigned to the subjects. For this purpose, zinc and placebo packages will be divided into A and B groups by someone outside the study.

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

Province

Khuzestan

Postal code

6135715794

Approval date

2022-10-08, 1401/07/16

Ethics committee reference number

IR.AJUMS.REC.1401.296

Health conditions studied

1

Description of health condition studied

allergic asthma

ICD-10 code

آسم آلرژیک

ICD-10 code description

J45.0

Primary outcomes

1

Description

IL-35

Timepoint

Before and two months after intervention

Method of measurement

ELISA

2

Description

TAC

Timepoint

Before and two months after intervention

Method of measurement

ELISA

3

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

Serum Zinc

Timepoint

Before and two months after intervention

Method of measurement

Serum Biochemistry Test/ Micro gr/ dl

2

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

3

Description

complete blood cell count and differential count

Timepoint

Before and two months after intervention

Method of measurement

Based on laboratory measurement

Intervention groups

1

Description

Intervention group:

Category

Treatment - Drugs

2

Description

Control group:

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Asthma and allergy doctor's office

Full name of responsible person

Marzie Zilaei

Street address

Ahvaz Jundishapur University of Medical Sciences,
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Dr Mehrnoosh Zakerkish

Street address

Vice Chancellor for Research and Technology, 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

Pardis Tofighzadeh

Position

M.Sc student of Nutrition Science

Latest degree

Bachelor

Other areas of specialty/work

Nutrition

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Marzie Zilaei

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Assistant Professor

Latest degree

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Latest degree

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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

The person's information will be confidential and the results will be as collective statistics

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