Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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

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.

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

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.

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

Intervention groups
Study groups include zinc gluconate and placebo consumer groups

Main outcome variables
IL-35; TAC; FEV1, FVC, FEV1/FVC

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220507054764N1**
Registration date: **2022-11-02, 1401/08/11**
Registration timing: **prospective**

Last update: **2022-11-02, 1401/08/11**
Update count: **0**

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

Registrant information

Name
Pardis Tofighzadeh

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 61 3311 2666

Email address
tofighzadeh.p@ajums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-11-22, 1401/09/01

Expected recruitment end date
2023-05-04, 1402/02/14

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

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
Khouzestan
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 Zilaee
Street address
Ahvaz Jundishapur University of Medical Sciences, Golestan street
City
Ahvaz
Province
Khouzestan
Postal code
1579461357
Phone
+98 61 3336 2414
Email
zilaee-m@ajums.ac.ir

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 Jundishapur University of Medical Sciences, Golestan street, Ahvaz
City
Ahvaz
Province
Khouzestan
Postal code
15794-61357
Phone
+98 61 3336 2414
Email
itc@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
Pardis Tofighzadeh
Position
M.Sc student of Nutrition Science
Latest degree
Bachelor
Other areas of specialty/work
Nutrition

Street address
Department of Nutrition, School of Allied Medical Sciences, Ahvaz Jundishapur University of Medical Sciences, Golestan St., Ahvaz
City
Ahvaz
Province
Khouzestan
Postal code
6135715794
Phone
+98 61 3571 5794
Email
pardistofigh@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Marzie Zilaee
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Nutrition
Street address
Department of Nutrition, School of Allied Medical Sciences, Jundishapur University of Medical Sciences, Golestan St., Ahvaz
City
Ahvaz
Province
Khouzestan
Postal code
6135715794
Phone
+98 61 3311 2713
Email
zilaee-m@ajums.ac.ir

Person responsible for updating data

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
Street address
Department of Nutrition, School of Allied Medical Sciences, Ahvaz Jundishapur University of Medical Sciences, Golestan St., Ahvaz
City
Ahvaz
Province
Khouzestan
Postal code
6135715794
Phone
+98 61 3311 2713
Email
pardistofigh@gmail.com

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