Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

The effect of nanocurcumin and omega-3 supplementation on quality of life in patients with asthma

Protocol summary

Study aim
Our study aims to identify an adjunctive therapy for asthma patients that is both cost-effective and safe to limit the need to add more expensive drug therapies such as biologics.

Design
A clinical trial with a control group and a double-blind randomized trial on 88 patients ANCOVA will be used to investigate the effect of intervention on quantitative outcomes for controlling confounding variables. Blocks of four were done based on age classification.

Settings and conduct
The study will be conducted in a double-blind manner at Hazrat Rasool Akram Hospital. Food recall, quality of life questionnaires, asthma control questionnaires, international physical activity questionnaires, consent forms, and general information will be recorded before and after the intervention.

Participants/Inclusion and exclusion criteria
Inclusion criteria: 1) Patients with asthma diagnosed by a doctor 2) Asthma patients with an age range of 15 to 60 years Non-entry criteria: 1) Users of systemic drugs, immunosuppressive drugs 2) People with COPD, cardiovascular disease, kidney disease, digestive disease, liver disease, autoimmune disease, reflex 3) Pregnant and lactating women 4) Addicted people and tobacco users, including hookah and smoking, etc. 5) Allergy/intolerance to curcumin, fish oil 6) Consumption of food supplements and antioxidants from 2 months before and during the study

Intervention groups
The intervention group consumes a 40 mg nanocurcumin supplement and a 1000 mg omega _3 daily for 8 weeks. The control group consumes a placebo 40mg nanocurcumin and a placebo 1000mg omega_3 daily for 8 weeks.

Main outcome variables
Quality of life of patients with asthma. Measurement of exhaled nitric oxide through the FeNo device

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20191105045340N3**
Registration date: **2023-07-11, 1402/04/20**
Registration timing: **prospective**

Last update: **2023-07-11, 1402/04/20**
Update count: **0**

Registration date
2023-07-11, 1402/04/20

Registrant information

Name
Seyedeh Tayebeh Rahideh

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-08-23, 1402/06/01

Expected recruitment end date
2024-10-22, 1403/08/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

The effect of nanocurcumin and omega-3 supplementation on quality of life in patients with asthma

Public title
the effect of nanocurcumin and omega_3 supplement in asthma
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with asthma diagnosed by a doctor Asthma patients with an age range of 15 to 60 years
Exclusion criteria:
Users of systemic drugs, NSAIDs, immunosuppressive drugs NSAID users Users of immunosuppressive drugs People with COPD Cardiovascular patients Kidney patients Liver patients Gastrointestinal patients Autoimmune patients suffering from reflexes Lactating lady pregnant lady People addicted to tobacco Allergy and intolerance to curcumin Allergy and intolerance to fish oil Consumption of food supplements and antioxidants from 2 months before and during the study
Age
From **15 years** old to **60 years** old
Gender
Both

Phase
3
Groups that have been masked

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

Sample size
Target sample size: **88**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients who meet the criteria for entering the study will be divided to groups A and B, based on a randomized list (by the method of blocks of four obtained from the Random number calculator computer program). In order to make a placebo, coordination will be done with Karen and Elixir Nano Sina pharmaceutical companies And it is requested that the drug manufacturer put one of the letters A or B on the drug or placebo and the other letters on the other by using a lottery by throwing a coin.
Blinding (investigator's opinion)
Double blinded
Blinding description
This interventional study will be conducted in a double-blind manner. Blinding includes patients and researchers. Coordination will be done with Karen and Vaxir Nano Sina pharmaceutical companies for the preparation of the placebo. The drug manufacturer will place one of the letters A or B on the drug or placebo by throwing a coin, and this will be kept confidential until the end of the intervention. It keeps itself. That means the therapist will not know whether the package is a supplement or a placebo. The placebo capsules will be completely similar to the capsules of the intervention group in terms of color, smell and shape.
Placebo
Used
Assignment
Parallel
Other design features
The aim of our study is to identify an adjunctive therapy that is both cost-effective and safe for asthma patients to limit the need to add more expensive drug therapies such as biologics.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Iran University of Medical Sciences
Street address
Hammet highway, next to Milad Tower, Iran University of Medical Sciences, Research and Technology Vice-Chancellor, Research Development and Evaluation Directorate
City
Tehran
Province
Tehran
Postal code
88622703
Approval date
2023-06-26, 1402/04/05
Ethics committee reference number
IR.IUMS.REC.1402.260

Health conditions studied

1

Description of health condition studied
Asthma
ICD-10 code
J45
ICD-10 code description
Asthma

Primary outcomes

1

Description
Quality of life of patients with asthma
Timepoint
Before the intervention and 8 weeks after the intervention
Method of measurement

Asthma control questionnaire

2

Description
Measurement of airway inflammation in patients with asthma
Timepoint
Before the intervention and 8 weeks after the intervention
Method of measurement
Measurement of exhaled nitric oxide through the FeNo device

Secondary outcomes

1

Description
Quality of life questionnaire score of patients with asthma
Timepoint
Before the intervention and 8 weeks after the intervention
Method of measurement
Evaluation of the quality of life questionnaire

Intervention groups

1

Description
Intervention group: Take a 40 mg nanocurcumin capsule (Elixir Nanosina pharmaceutical company) and a 1000 mg omega-3 capsule (Karen pharmaceutical company) daily for 8 weeks.
Category
Treatment - Other

2

Description
Control group: a 40mg nanocurcumin placebo containing starch (Elixir Nano Sina Pharmaceutical Company) and a 1000mg Omega 3 placebo containing paraffin (Karen Pharmaceutical Company) are taken daily for 8 weeks.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Hazrat Rasool Akram Hospital
Full name of responsible person
Seyedeh Tayebeh Rahideh
Street address
Sattar Khan St., Niayesh St., corner of Mansouri St., Hazrat Rasool Akram Hospital
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
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Street address
Hemat Highway, next to Milad Tower, Iran University of Medical Sciences, 5th floor of Iran University of Medical Sciences headquarters building
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Iran 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
Iran University of Medical Sciences
Full name of responsible person
Seyedeh tayebeh rahideh
Position
Assistant Professor
Latest degree

Ph.D.

Other areas of specialty/work
Nutrition

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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