

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 Tayebbeh Rahideh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8670 4843

Email address

rahide.t@iums.ac.ir

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 Tayebbeh Rahideh

Street address

Sattar Khan St., Niayesh St., corner of Mansouri St., Hazrat Rasool Akram Hospital

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Rasoolhospital@iums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Reza falak

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 tayebbeh rahideh

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Person responsible for scientific inquiries

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Full name of responsible person

seyedeh Tayebbeh Rahideh

Position

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Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Person responsible for updating data

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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