

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Investigation of effect of oral nanomicell curcumin on Improving of FEV1 and Quality of Life in Patients with Non-atopic Bronchial Asthma

Protocol summary

Study aim

Improving of asthma symptoms by using curcumin along with standard asthma medications

Design

A total of 60 patients with bronchial asthma, referred to the Pulmonary Disease Research Center, were enrolled on the Inclusion and exclusion criteria, and then the patients were randomly assigned to two groups according to a random number table using the envelope. At first, a checklist for demographic information, history of asthma, full history of the drug, and ... are completed for patients.

Settings and conduct

At first, a checklist for demographic information, a history of asthma, a full history of the drug, and ... for patients is completed. The ACT, AQLQ questionnaire is then used to control of asthma. Spirometry is first performed. Then, 5 cc of brachial venous blood is taken in fasting state and the sample is sent to the liver count, liver, kidney tests. The drug and placebo groups were randomly assigned and the first group received the standard treatment of asthma + curcumin 40 mg three times a day and the second group received standard asthma + placebo treatment three times a day. The study was performed in a double blind clinical trial

Participants/Inclusion and exclusion criteria

Non-atopic asthmatic patients over 18 years of age without chronic underlying disease

Intervention groups

The first group received the standard treatment of asthma + curcumin 40 mg three times /day and the second group received standard asthma + placebo treatment three times / day.

Main outcome variables

FEV1,ACT,AQLQ

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20161226031584N2**

Registration date: **2019-06-17, 1398/03/27**

Registration timing: **retrospective**

Last update: **2019-06-17, 1398/03/27**

Update count: **0**

Registration date

2019-06-17, 1398/03/27

Registrant information

Name

Shahrzad Mohammadzadeh Lari

Name of organization / entity

Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 51 3801 2742

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larish@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-08-23, 1396/06/01

Expected recruitment end date

2019-09-23, 1398/07/01

Actual recruitment start date

2017-09-23, 1396/07/01

Actual recruitment end date

2018-09-23, 1397/07/01

Trial completion date

2019-04-21, 1398/02/01

Scientific title

Investigation of effect of oral nanomicell curcumin on Improving of FEV1 and Quality of Life in Patients with

Non-atopic Bronchial Asthma	
Public title	Investigation of effect of Oral Nanomicelle Curcumin in Patients with Non-atopic Bronchial Asthma
Purpose	Treatment
Inclusion/Exclusion criteria	Inclusion criteria: non atopic asthma informed consent Exclusion criteria: smoker COPD pregnancy/lactation heart ,liver,kidney disorder and gallbladder disease acute exacerbation within one month ago
Age	From 18 years old
Gender	Both
Phase	3
Groups that have been masked	• Participant • Care provider • Investigator • Outcome assessor • Data analyser
Sample size	Target sample size: 60 Actual sample size reached: 60
Randomization (investigator's opinion)	Randomized
Randomization description	Simple randomization, randomization method :(Random Concealment)
Blinding (investigator's opinion)	Double blinded
Blinding description	A random allocation was made after explaining how to conduct the research and obtaining informed consent from patients. The type of treatment prescribed for each patient (in the form of Paired and odd numbers or code A, B) was written in tabs and each sheet was placed in an envelope. After the patient's visit, if the patient has inclusion criteria, then he will remove the random concealment after explaining how the doctor will study. The checklist for demographic information and questionnaires used in the project is completed with the help of the researcher. The assigned number (Paired and odd numbers) is given to the patient (the blind doctor) and how they are used. The researcher records the delivered drug code (Paired and odd numbers). Due to the fact that the placebo is in every way similar to intervention, patients will not be aware of which group they are (patients are blind). After collecting the data, the analyzer analyzes the data according to their code (paired or individual). They (the evaluator and analyzer) will not be aware of the treatment.
Placebo	Used
Assignment	Parallel

Other design features	nanomicell curcumin
Secondary Ids	empty
Ethics committees	
<u>1</u>	
Ethics committee	
Name of ethics committee	The code of ethics is "IR.MUMS.fm.REC.1395.259" and the date of approval is 03/04/1395.
Street address	Ahmadabad steet
City	Mashhad
Province	Razavi Khorasan
Postal code	The code of ethics i
Approval date	2016-06-23, 1395/04/03
Ethics committee reference number	The code of ethics is "IR.MUMS.fm.REC.1395.259" and the date of approval is 03/04/1395.
Health conditions studied	
<u>1</u>	
Description of health condition studied	Asthma
ICD-10 code	J40-J47
ICD-10 code description	Chronic lower respiratory diseases
Primary outcomes	
<u>1</u>	
Description	FEV1,ACT ,AQLQ
Timepoint	Measuring the FEV1-ACT, AQLQ questionnaire every two weeks to two months.
Method of measurement	questionnaire ,spirometry,physical exam
Secondary outcomes	empty
Intervention groups	
<u>1</u>	
Description	Interventional group:Oral curcumin 40 mg three times a

day (Sinacurcumin nanomicelle, Minoo Pharmacy Company, Tehran, Iran) as an Add-on therapy in Patients of Bronchial Asthma that the patient received in the past.

Category

Treatment - Drugs

2

Description

Control group: The placebo(which appears to be completely similar to the drug)was given three times daily as an Add-on therapy in Patients of Bronchial Asthma that the patient received in the past

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Ghaem hospital

Full name of responsible person

Shahrzad mohamadzadeh lari

Street address

Pulmonary Diseases Research Center, Ghaem Hospital, Ahammad Abad Ave.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Research and Technology Deputy.

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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

Pulmonary Diseases Research Center

Proportion provided by this source

100

Public or private sector

Private

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

Mashhad University of Medical Sciences

Full name of responsible person

Shahrzad Mohamadzadeh Lari

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Pulmonologist

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Subspecialist
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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