Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Evaluation of the Effectiveness of Nanomicelle Curcumin Formulation on Clinical and Spirometry Parameters of Asthma in Children

Protocol summary

Study aim
Evaluation of the Effectiveness of Nanomicelle Curcumin Formulation on Clinical and Spirometry Parameters of Asthma in Children

Design
Clinical trial with control group, with parallel groups, double blinded, randomized, phase 2-3 on 90 patients with asthma. Block randomization was used.

Settings and conduct
This study will be performed as a double-blind clinical trial in two groups of intervention and control on 90 children with asthma referred to allergy subspecialized clinic of Akbar hospital. Patients will be randomly assigned to one of two intervention or control groups. Patients in both groups will receive standard asthma treatment along with curcumin syrup (intervention group) or placebo syrup (control group).

Participants/Inclusion and exclusion criteria
Inclusion criteria : Pediatric patients (6-12 years old) referred to allergy subspecialized clinic of Akbar hospital with mild persistent asthma, Obtain informed consent of patient/caregiver Exclusion criteria : Patient with lung infection, Patients with underlying cardiac, hepatic, biliary, renal, or gastrointestinal diseases or allergic rhinitis, Taking anticoagulants such as warfarin or antiplatelet, Diabetic patients, Child with smoking parent

Intervention groups
In intervention group, asthmatic patients will receive standard treatment along with curcumin syrup at a dose of 40 mg daily for two months. In control group, asthmatic patients will receive standard treatment along with a volume equivalent of placebo syrup daily for two months. Medication and placebo are provided by the Exir Nano Sina company.

Main outcome variables
Patients' clinical signs score in asthma control questionnaire, Value of Forced expiratory volume in one second (FEV1), Forced Vital Capacity (FVC), FEV1 / FVC, Maximal Mid-Expiratory Flow rate (MMEF25-75)

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20191221045837N3**
Registration date: **2020-10-24, 1399/08/03**
Registration timing: **prospective**

Last update: **2020-10-24, 1399/08/03**
Update count: **0**

Registration date
2020-10-24, 1399/08/03

Registrant information

Name
Zinat Heidari

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 51 3180 1584

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-11-05, 1399/08/15

Expected recruitment end date
2022-11-06, 1401/08/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Evaluation of the Effectiveness of Nanomicelle Curcumin Formulation on Clinical and Spirometry Parameters of Asthma in Children

Public title
Effect of Nanomicelle Curcumin in pediatric asthma
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Pediatric patients admitted to allergy subspecialized clinic of Akbar hospital 6-12 years old With mild persistant asthma based on Global Initiative for Asthma (GINA) 2019 guideline Informed consent of patient/caregiver
Exclusion criteria:
Patients with pulmunary infection Patients with underlying cardiac, hepatic, biliary, renal, or gastrointestinal diseases or allergic rhinitis Patients with smoker parents Patients taking anticoagolant or antiplatelet medications Patients with diabetes
Age
From **6 years** old to **12 years** old
Gender
Both

Phase
2-3
Groups that have been masked

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

Sample size
Target sample size: **90**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization method: Block randomization Randomization tool: https://www.sealedenvelope.com/ How to make a random sequence: To perform this method, the number of intervention groups (two groups A and B), the volume of each block (6 in each block) and the number of sample size (90 patients) were entered into the website. The site then provided a list of 15 blocks, each contains 6 patients. In this study, we use 6 patients in each block and the website randomizes and numbers the blocks. Allocation Concealment Method: Sealed Envelopes
Blinding (investigator's opinion)
Double blinded
Blinding description
The study is double-blinded in which the patients, evaluators, analysts, sample allocators will be unaware of the intervention and control groups. The medication and placebo will be produced in the same dosage form and packaging by the manufacturer and will be numbered according to a random list. Physicians, patients, and analyst will remain unaware of the type of drug or placebo formulation until the work is completed. At the beginning of the study, the patient will be explained that he or she may be in the medication or placebo group.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Mashhad University of Medical Sciences
Street address
Central department of Mashhad University of Medical Sciences, next to Alton Tower, Daneshgah Street, Mashhad, Khorasan Razavi Province
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Province
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Postal code
13944-91388
Approval date
2019-12-07, 1398/09/16
Ethics committee reference number
IR.MUMS.REC.1398.250

Health conditions studied

1

Description of health condition studied
asthma
ICD-10 code
J45.3
ICD-10 code description
Mild persistent asthma

Primary outcomes

1

Description
Patients' clinical signs score in asthma control questionnaire (c-ACT)
Timepoint
At baseline and end of the study (end of the second month)
Method of measurement
Asthma Control Questionnaire

2

Description

Maximal Mid-Expiratory Flow rate (MMEF25-75)

Timepoint

At baseline and end of the study (end of the second month)

Method of measurement

spirometry test

3

Description

Value of Forced expiratory volume in one second (FEV1)

Timepoint

At baseline and end of the study (end of the second month)

Method of measurement

spirometry test

4

Description

Value of Forced Vital Capacity (FVC)

Timepoint

At baseline and end of the study (end of the second month)

Method of measurement

spirometry test

5

Description

Ratio of Forced expiratory volume in one second (FEV1)/Value of Forced Vital Capacity (FVC)

Timepoint

At baseline and end of the study (end of the second month)

Method of measurement

spirometry test

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In the intervention group, asthmatic patients will receive standard treatment of asthma (based on asthma severity and according to the Global Initiative for Asthma (GINA) 2019 Guidelines) along with curcumin syrup at a dose of 40 mg (1 ml) orally daily for two months. In this study, Sina curcumin product in syrup formulation (made by Exir Nano Sina Company) will be used. Medication and placebo are provided by the company. Curcumin syrup is prepared at a concentration of 40 mg/ml.

Category

Treatment - Drugs

2

Description

Control group: In the control group, asthmatic patients will receive standard treatment of asthma (based on asthma severity and according to the Global Initiative for Asthma (GINA) 2019 Guidelines) along with the volume equivalent of placebo syrup (1 ml) orally daily for two months. Medication and placebo are provided by the Exir Nano Sina company.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Akbar pediatric hospital

Full name of responsible person

Zinat Heidari

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Akbar pediatric hospital, Shahid Kaveh Boulevard, Mashhad, Khorasan Razavi.

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Sponsors / Funding sources

1

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Full name of responsible person

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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
Mashhad 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
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Position
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Latest degree
Specialist
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
After the end of the study, data collection and data

transfer to SPSS software, data can be shared.

When the data will become available and for how long

Access period starts 6 months after the results are published

To whom data/document is available

Researchers working in academic, scientific and industrial institutes

Under which criteria data/document could be used

No one is allowed to use the documents except the principal investigator.

From where data/document is obtainable

Send an email to Dr. Zeinat Heydari. heidarizn@mums.ac.ir

What processes are involved for a request to access data/document

Send an email to Dr. Zeinat Heydari. heidarizn@mums.ac.ir

Comments