Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Dec 2023

Evaluation of the effects of curcumin-piperine in reducing Pseudomonas infection and improving clinical outcome in patients with cystic fibrosis

Protocol summary

Study aim

Determining effect of curcumin-piperine drug on Pseudomonas infection and clinical symptoms of cystic fibrosis patients

Design

A clinical trial with a control group, with parallel groups, double-blind, randomized,

Settings and conduct

Study population is the patients referred to the cystic fibrosis clinic in Akbar Children's Hospital. Patients are divided into case and control groups. Curcumin-piperine is given to case group and placebo with the usual treatments is given to control group . The duration of the treatment period will be 3 months. The results will be checked at the beginning and end of the treatment.

Participants/Inclusion and exclusion criteria

Entry conditions: Cystic fibrosis patients who have been diagnosed based on clinical symptoms and sweat test, 5 years and above, Have pulmonary and gastrointestinal problems, able to perform the spirometry maneuver and have at least FEV1≥ 30% based on normal population based on age, gender,height, Percentage of oxygen saturation based on pulse oximetry be≥90% at room temperature,be clinically stable, Informed consent has been obtained from the patients,Do not have heart,liver,kidney failure, Do not have celiac disease, No evidence of acute pulmonary exacerbation that requiring hospitalization in last4 weeks, Do not have evidence of severe complications of pulmonary disease including severe hemoptysis or pneumothorax during last 2 months

Intervention groups

Intervention group: the intervention group are cystic fibrosis patients with pseudomonas infection who are treated with curcumin-piperine in addition to the usual treatments for cystic fibrosis.control group are patients with cystic fibrosis who are treated with placebo in addition to the usual treatments of cystic fibrosis.

Main outcome variables

Clinical symptoms of patients,Pulmonary symptoms,Pseudomonas pulmonary infection,Weight,Height,Body mass index,Patients' quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221229056976N1**
Registration date: **2023-01-26, 1401/11/06**
Registration timing: **prospective**

Last update: **2023-01-26, 1401/11/06**
Update count: **0**

Registration date

2023-01-26, 1401/11/06

Registrant information

Name

Rasool Mohammadi

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 51 4334 9745

Email address

reysoolmdi1376@gmail.com

Recruitment status

recruiting

Funding source

Expected recruitment start date

2023-03-05, 1401/12/14

Expected recruitment end date

2024-03-04, 1402/12/14

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of the effects of curcumin-piperine in reducing Pseudomonas infection and improving clinical outcome in patients with cystic fibrosis

Public title
Evaluation of the effects of curcumin-piperine in reducing Pseudomonas infection and improving clinical outcome in patients with cystic fibrosis
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Cystic fibrosis patients who have been diagnosed based on clinical symptoms and sweat test. 5 years and above. Have pulmonary and gastrointestinal problems. able to perform the spirometry maneuver and have at least FEV1 greater than or equal to 30% based on the normal population based on age, gender and height. The percentage of oxygen saturation based on pulse oximetry should be greater than or equal to 90% at room temperature. be clinically stable. Informed consent has been obtained from the patients. Do not have heart, liver or kidney failure. Do not have celiac disease. No evidence of acute pulmonary exacerbation that requiring hospitalization in last past 4 weeks. Do not have evidence of severe complications of pulmonary disease including severe hemoptysis or pneumothorax during the last 2 months.
Exclusion criteria:
Age
From **5 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **138**
Randomization (investigator's opinion)
Randomized
Randomization description
The samples will be determined by random block method with blocks of 4 and using random numbers table of SAS software. Blocking and allocation sequence for concealment will be done by a person not involved in the research. The allocation ratio of the samples will be (Allocation 1:1) and will be placed in two groups (Assignment). Then, based on the obtained blocks and according to the allocation sequence, the drugs will be given to the patients.
Blinding (investigator's opinion)
Double blinded
Blinding description
To blind the participants, a placebo will be used with packaging, color, size and other appearance characteristics completely similar to curcumin-piperine tablets. In order to blind the evaluators of the research team, as soon as the treatment or control group is determined in the randomization stage, a random code will be assigned to the participant (without including group A or B on the file) and they will be followed by this code in any stage of research. Finally, after evaluating and documenting the results ,the codes will be decoded.
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
Shahid Fakouri Blvd, Mashhad, Iran
City
Mashhad
Province
Razavi Khorasan
Postal code
91778-99191
Approval date
2022-11-08, 1401/08/17
Ethics committee reference number
IR.MUMS.MEDICAL.REC.1401.512

Health conditions studied

1

Description of health condition studied
cystic fibrosis
ICD-10 code
E84
ICD-10 code description
Cystic fibrosis

Primary outcomes

1

Description
Evaluation of clinical symptoms of patients
Timepoint
In each visit
Method of measurement
Based on Shwachman-Kulczycki Score

2

Description
Evaluation of pulmonary symptoms
Timepoint
Every 3 to 6 months
Method of measurement
Based on spirometry

3

Description
Evaluation of Pseudomonas pulmonary infection
Timepoint
Every 3 months
Method of measurement
With nasopharyngeal swab sample (sputum culture and colony count)

4

Description
Weight
Timepoint
In each visit
Method of measurement
Weighing scale

5

Description
Height
Timepoint
In each visit
Method of measurement
Meter

6

Description
Body mass index (BMI)
Timepoint
In each visit
Method of measurement
Body weight (kg) divided by the square of the body height(m)

7

Description
Evaluation of patients' quality of life
Timepoint
Yearly
Method of measurement
Based on the quality of life questionnaire of cystic fibrosis patients

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: the intervention group are cystic fibrosis patients with pseudomonas infection who are treated with curcumin-piperine in addition to the usual treatments for cystic fibrosis. The duration of the treatment period will be 3 months. Curcumin-piperine is prepared in the form of 500 mg capsules with 5 mg of piperine as an absorption enhancer (Sami Labs Ltd., India) and is given to cystic fibrosis patients along with the usual treatments.
Category
Treatment - Drugs

2

Description
Control group: The control group are patients with cystic fibrosis who are treated with placebo in addition to the usual treatments of cystic fibrosis. placebo tablets containing microcrystalline cellulose matched in size, shape and color to the curcuminoids tablets
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Akbar Hospital
Full name of responsible person
Dr. Saeedeh Talebi
Street address
Kaveh Blvd, Region 9, Mashhad
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ak.pr@mums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Majid Ghayour Mobarhan
Street address
Azadi Square, Mashhad
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ghayourm@mums.ac.ir

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

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Saeedeh Talebi

Position
Associate professor

Latest degree
Specialist

Other areas of specialty/work
Pediatrics

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Akbar Hospital,Kaveh Blvd, Region 9, Mashhad

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Person responsible for scientific inquiries

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Position
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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