Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of the efficiency of nanomicellar formulation with standard formulation of fat-soluble vitamins in patients with cystic fibrosis

Protocol summary

Study aim

The aim of this study is to evaluate the efficiency of nanomicellar form of fat-soluble vitamins in patients with cystic fibrosis and also evaluating of the effectiveness of improving the serum level of fat-soluble vitamins, complications of fat-soluble vitamins deficiency, quality of life in cystic fibrosis patients and Anthropometric criteria (height, weight, and BMI) in the use of nanomicellar form of fat-soluble vitamins compared to the standard form

Design

Two arm parallel group randomized trial, one way blinded and phase 3 on 74 patients. Excel software or dedicated randomization sites will be used for randomization

Settings and conduct

The study site is Cystic Fibrosis Clinic in Akbar Children's Hospital. The duration of the study is 3 months. Only the data analyzer will be unaware of the intervention and control group.

Participants/Inclusion and exclusion criteria

Inclusion criteria include patients with cystic fibrosis over 8 years old who have been diagnosed based on clinical signs and sweat test, have pulmonary and gastrointestinal problems, have an oxygen saturation greater than or equal to 90%, be in clinically stable condition, and have informed consent; Exclusion criteria include patients with cystic fibrosis who have heart, liver, or kidney failure, patients with celiac disease, or who do not follow the medical treatment.

Intervention groups

The intervention group is patients with cystic fibrosis who use drops containing a combination of nanomicellar form of fat-soluble vitamins with a daily dosage of 1 cc; The control group is patients with cystic fibrosis who receive each of the fat-soluble vitamins in a standard and separate form with the appropriate dosage for cystic fibrosis patients

Main outcome variables

Measurement of serum levels of fat-soluble vitamins; Evaluation of patients' clinical symptoms, growth status, quality of life, and treatment adherence

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220415054541N1**
Registration date: **2022-07-23, 1401/05/01**
Registration timing: **prospective**

Last update: **2022-07-23, 1401/05/01**
Update count: **0**

Registration date

2022-07-23, 1401/05/01

Registrant information

Name

Mahsa Soleimanzadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3763 6773

Email address

soleimanzadehm951@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-08-23, 1401/06/01

Expected recruitment end date

2022-11-22, 1401/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the efficiency of nanomicellar formulation with standard formulation of fat-soluble vitamins in patients with cystic fibrosis

Public title

Evaluation of the efficiency of nanomicellar formulation of fat-soluble vitamins in cystic fibrosis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with cystic fibrosis who have been diagnosed based on clinical signs and sweat test Age 8 years and above Have pulmonary and gastrointestinal problems Oxygen saturation percentage based on pulse oximetry is greater than or equal to 90% at room temperature Be in clinically stable condition Have informed consent to participate in the study

Exclusion criteria:

The patient with heart, liver or kidney failure The patient with celiac disease The patient who do not follow medical treatment

Age

From **8 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **74**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization is done in a simple and individual way. Randomization is done using Excel software or dedicated randomization sites such as www.randomization.com, and two groups are identified as A and B or even and odd codes. According to the obtained sequence, we put the numbers in the sealed envelopes, and when the patients visit the clinic, one of the envelopes is selected, and according to the code written in it, the patient is placed in the intervention or control category

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not 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

3rd Floor, No. 31, Khayyam 24 St., Khayyam Blvd.

City

Mashhad

Province

Razavi Khorasan

Postal code

9187683999

Approval date

2022-05-17, 1401/02/27

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1401.116

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

Serum level of fat-soluble vitamins

Timepoint

Measurement of serum level of fat-soluble vitamins once at the beginning of the study (before the intervention) and once at the end of the study (3 months after the starting of intervention)

Method of measurement

Blood test

Secondary outcomes

1

Description

Clinical symptoms of patients

Timepoint

At the end of the study (3 months after the starting of intervention)

Method of measurement

Shwachman-Kulczycki Score (an indicator for assessing the severity of the disease in cystic fibrosis patients) which includes general activity, physical examination, nutrition and radiological findings

2

Description
Growth status
Timepoint
Once at the beginning of the study (before the intervention) and once at the end of the study (3 months after the starting of intervention)
Method of measurement
Based on changes in weight, height and Body mass index

3

Description
Quality of life score
Timepoint
At the end of the study (3 months after the starting of intervention)
Method of measurement
Cystic fibrosis patients' quality of life questionnaire

4

Description
The adherence to treatment
Timepoint
At the end of the study (3 months after the starting of intervention)
Method of measurement
The number of days she/he has taken the medicine

Intervention groups

1

Description
Intervention group: Patients with cystic fibrosis who use the drop containing the composition of nanomicellar formulation of vitamins A, D, E, and K at a daily dosage of 1 cc (each cc contains 1500 units of vitamin A, 3000 units of vitamin D, 150 units of vitamin E and 1000 micrograms of vitamin K) for 3 months
Category
Treatment - Drugs

2

Description
Control group: Patients with cystic fibrosis who use the standard formulation of vitamins A, D, E and K separately with appropriate dosage for cystic fibrosis patients (10,000 units of vitamin A, 5000 units of vitamin D, 400 units of vitamin E and 500 micrograms of vitamin K daily) for 3 months
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Akbar Children's Hospital
Full name of responsible person
Mahsa Soleimanzadeh
Street address
Akbar Children's Hospital, Shahid Fakouri 94 St., Shahid Fakouri Blvd., Knowledge and Health Town
City
Mashhad
Province
Razavi Khorasan
Postal code
9177897157
Phone
+98 51 3871 3801
Email
ak.pr@mums.ac.ir
Web page address
https://akbar.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
Mashhad University of Medical Sciences, Ferdowsi University Campus, Azadi Sq.
City
Mashhad
Province
Razavi Khorasan
Postal code
9138813944
Phone
+98 51 3841 1538
Email
vcresraech@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
Mahsa Soleimanzadeh

Position
Medical student

Latest degree
A Level or less

Other areas of specialty/work
General Practitioner

Street address
Floor. 3, No. 31, Alley. 24, South Khayyam Ave., Khayyam Blvd.

City
Mashhad

Province
Razavi Khorasan

Postal code
9187683999

Phone
+98 51 3763 6773

Fax

Email
soleimanzadehm951@mums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Mahsa Soleimanzadeh

Position
Medical student

Latest degree
A Level or less

Other areas of specialty/work
General Practitioner

Street address
Floor. 3, No. 31, Alley. 24, South Khayyam Ave., Khayyam Blvd.

City
Mashhad

Province
Razavi Khorasan

Postal code
9187683999

Phone
+98 51 3763 6773

Fax

Email
soleimanzadehm951@mums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Mahsa Soleimanzadeh

Position
Medical student

Latest degree
A Level or less

Other areas of specialty/work
General Practitioner

Street address
Floor. 3, No. 31, Alley. 24, South Khayyam Ave., Khayyam Blvd.

City
Mashhad

Province
Razavi Khorasan

Postal code
9187683999

Phone
+98 51 3763 6773

Fax

Email
soleimanzadehm951@mums.ac.ir

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