ongoing trials - trial from other registries

A Study To Evaluate The Safety Of CMTX-101 In People With Cystic Fibrosis - Phase 1|Phase 2 - Not yet recruiting

Code: NCT06159725 **Year:** 2023 **Date:** January 2023 **Author:** Clarametyx Biosciences, Inc.

Study design (if review, criteria of inclusion for studies)

Randomization: Randomized, Blinding: Double blinded, Placebo: Used, Assignment: Parallel, Purpose: Treatment, 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 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 o

Participants

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.

Interventions

Intervention 1: 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. Intervention 2: 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.

Outcome measures

Evaluation of pulmonary symptoms. Timepoint: Every 3 to 6 months. Method of measurement: Based on spirometry. Evaluation of patients' quality of life. Timepoint: Yearly. Method of measurement: Based on the quality of life questionnaire of cystic fibrosis patients. Evaluation of clinical symptoms of patients. Timepoint: In each visit. Method of measurement: Based on Shwachman-Kulczycki Score. Height. Timepoint: In each visit. Method of measurement: Meter. Weight. Timepoint: In each visit. Method of measurement: Weighing scale.

https://ClinicalTrials.gov/show/NCT06159725

Keywords

Curcumin; Supplementation; non pharmacological intervention - diet; Piperine;