ongoing trials - trial from other registries

Nebulized Bacteriophage Therapy in Cystic Fibrosis Patients With Chronic Pseudomonas Aeruginosa Pulmonary Infection - Phase 1|Phase 2 - Not yet recruiting

Code: NCT05010577 **Year:** 2021 **Date:** 44219 **Author:** BiomX, Inc.

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

Randomization: Randomized, Blinding: Double blinded, Placebo: Used, Assignment: Parallel, Purpose: Other, Randomization description: The randomization method is based on a table of random numbers and blocks of 4 and the study is double-blind, Blinding description: The compound honey syrup and placebo have been coded for blinding. The patient and researcher are unaware of the type of drug administered.

Participants

Inclusion criteria: Patients with cystic fibrosis with clinical signs of sinusitis over 6 years of age who refer to the pulmonary Clinic of Mofid Children's Hospital and enter the study with the informed consent of the parents of children and children over 6 years of age. Exclusion criteria: Patients with cystic fibrosis under 6 years of age referred to the pulmonary Clinic of the Mofid Children's Hospital, lack of clinical signs of sinusitis, patients in need of hospitalization and patients with increased cough, sputum and fever, and patients with underlying conditions such as allergic bronchopulmonary aspergillosis(ABPA) and Tuberculosis are not included in the study. Age minimum: 6 years Age maximum: no limit Gender: Both

Interventions

Intervention 1: Intervention group: In addition to all the standard and required medicines for the patient, in the experimental group, compound honey syrup is also prescribed. Consumption of compound honey syrup, 5-10 cc (according to the weight of children, in the weight of over 30 kg, 10 cc and in the low weight of 30 kg, 5 cc) in 100 cc of boiled and lukewarm twice a day 30 minutes after the meal. The study period is 12 weeks. Intervention 2: Control group: In addition to all the standard and required drugs for the patient, in the control group, placebo approved by the pharmaceutical group (containing sodium saccharin) is also prescribed. Consumption of placebo syrup is 5-10 cc (according to the weight of children, in the weight of over 30 kg, 10 cc and in the low weight of 30 kg, 5 cc) in 100 cc of boiled and lukewarm water twice a day 30 minutes after the meal.The study period is 12 weeks.

Outcome measures

Dizziness. Timepoint: At the beginning of the study, the end of the Sixth and twelfth week. Method of measurement: SNOT questionnair. Ear fullness. Timepoint: At the beginning of the study, the end of the Sixth and twelfth week. Method of measurement: SNOT questionnair. Ear pain. Timepoint: At the beginning of the study, the end of the Sixth and twelfth week. Method of measurement: SNOT questionnair. Facial pain/pressure. Timepoint: At the beginning of the study, the end of the Sixth and twelfth week. Method of measurement: SNOT questionnair. Nasal obstruction. Timepoint: At the beginning of the study, the end of the Sixth and twelfth week. Method of measurement: SNOT questionnair. Runny nose. Timepoint: At the beginning of the study(Before starting the intervention), the end of the Sixth and twelfth week. Method of measurement: SNOT questionnair.

https://ClinicalTrials.gov/show/NCT05010577

Keywords

honey; Adolescent; Adult; Bacterial Infections; Child; Infection; Respiratory Tract Infections; Sinusitis; Airway clearance drugs -expectorants- mucolytic- mucociliary-; Respiratory System Agents; Respiratory Tract Diseases; Dornase alpha; Pulmozyme; Hypertonic Solutions; Inhalation OR nebulised; pharmacological_intervention; isotonic Solutions;