ongoing trials - trial from www.clinicaltrials.gov

Estrogen Patches for Adolescent and Young Adult Women With Cystic Fibrosis - Phase 4 - Not yet recruiting

Code: NCT05704036 **Year:** 2023 **Date:** January 2023

Author: Johns Hopkins University|Cystic Fibrosis Foundation

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

Interventional - Allocation: Randomized|Intervention Model: Parallel Assignment|Masking: Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)|Primary Purpose: Treatment

Participants

Cystic Fibrosis|Hypoestrogenism - 16 Years to 30 Years (Child, Adult)

Interventions

Drug: Transdermal estrogen|Drug: Placebo patch|Drug: Progesterone|Drug: Placebo pill

Outcome measures

Number of potential participants enrolled per month. Rate of screen fails. Study procedure completion rate. Acceptability as determined by participant report. Change in serum estradiol levels (pg/mL). Change in serum procollagen type I intact N-terminal propeptide (P1NP) levels (mcg/L). Change in serum C-terminal telopeptide of type I collagen (CTX-1) levels (pg/mL). Change in lumbar spine bone mineral density assessed by dual-energy x-ray absorptiometry (DXA). Change in quality of life as assessed by Cystic Fibrosis Respiratory Symptom Diary - Chronic Respiratory Infection Symptom Score (CFRSD-CRISS) questionnaire

https://ClinicalTrials.gov/show/NCT05704036

Keywords

estrogens; estradiol; Hormones; pharmacological_intervention;