A221102

Randomized Double-Blind Placebo Controlled Study of Testosterone in the Adjuvant Treatment of Postmenopausal Women with Aromatase Inhibitor Induced Arthralgias

ClinicalTrial.gov Identifier: NCT01573442

Study Background

Trial Description

This randomized phase III trial studies testosterone to see how well it works compared to placebo in treating postmenopausal patients with arthralgia (joint pain) caused by anastrozole or letrozole. Testosterone may help relieve moderate or severe arthralgia associated with the use of aromatase inhibitors, such as anastrozole or letrozole.

Arms:

Arm I: (Experimental): Patients receive testosterone (0.264mL) topical application daily for six months.

Arm II: (Placebo Comparator): Patients receive placebo (0.264mL) topical application daily for six months.

Objectives:

This is a randomized, placebo-controlled, phase III trial evaluating subcutaneous testosterone for the alleviation of aromatase inhibitor induced arthralgia. A parallel group design will be utilized for this two-arm study: subcutaneous testosterone vs. placebo. Patients are stratified according to baseline pain score (5-6 vs. 7-10) and age (< 50 vs. 50-60 vs. > 60). The primary objective is to determine whether testosterone will reduce AI-induced arthralgia and associated joint symptoms. The secondary objective is to explore whether testosterone will have an acceptable safety and tolerability profile, with particular reference to androgenic adverse events including acne, hirsutism, and alopecia. Patients are followed up to six months as defined in the protocol.

Study Milestones:

Primary Completion Date: February 28, 2018

Publication Information:

Analysis Type: Primary

Pubmed ID: 32372176

Citation: Cathcart-Rake, E., Novotny, P., Leon-Ferre, R. et al. A randomized, double-blind, placebo-controlled trial of testosterone for treatment of postmenopausal women with aromatase inhibitor-induced arthralgias: Alliance study A221102. Support Care Cancer 29, 387 396 (2021). https://doi.org/10.1007/s00520-020-05473-2

Associated Datasets:

NCT01573442-D1-Dataset.csv (consort),

NCT01573442-D2-Dataset.csv (baseline),

NCT01573442-D3-Dataset.csv (avg_bpi),

NCT01573442-D4-Dataset.csv (repeated_BPI),

NCT01573442-D5-Dataset.csv (figure2),

NCT01573442-D6-Dataset.csv (qol3),

NCT01573442-D7-Dataset.csv (sed),

NCT01573442-D8-Dataset.csv (supplemental2),

NCT01573442-D9-Dataset.csv (Hotflash),

NCT01573442-D10-Dataset.csv (hotflash_sub),

NCT01573442-D11-Dataset.csv (subcut),

NCT01573442-D12-Dataset.csv (figure_supplemental),

NCT01573442-D13-Dataset.csv (gene_analysis),

NCT01573442-D14-Dataset.csv (supplemental3)

Dataset Information:

Dataset Name: NCT01573442-D10-Dataset.csv (hotflash_sub)

Description: Dataset NCT01573442-D10-Dataset.csv (hotflash_sub) is one of 14 datasets associated with PubMed ID 32372176. This dataset contains information on hot flash scores for patients receiving subcutaneous treatment.

Data can be used to approximate published study findings, but exact reproduction of previous manuscripts may not be possible in some cases (e.g., when data must be modified for de-identification purposes or have undergone further data cleaning).

Blank values indicate data not applicable or missing, except where otherwise noted.

NCT01573442-D10-Dataset.csv (hotflash_sub) Data Dictionary:

LABEL	NAME	ELEMENTS	COMMENTS
Patient ID	patref		
Hot Flash Score	p_hf_sc		Percent change from baseline
Week	week	0, 1, 2, 3, 4, 5, 6, 7, 8	
Arm	Arm	Testosterone, Placebo	