

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-D7-Dataset.csv (sed)

Description: Dataset NCT01573442-D7-Dataset.csv (sed) is one of 14 datasets associated with PubMed ID 32372176. This dataset contains information on the symptom experience diary (SED).

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-D7-Dataset.csv (sed) Data Dictionary:

LABEL	NAME	ELEMENTS	COMMENTS
Patient ID	patref		
Arm	arm	Testosterone, Placebo	
Month 3: Maximum score for Stomach Pain or Cramps	sed1_max		On a scale 0-10
Month 3: Maximum score for Diarrhea	sed2_max		On a scale 0-10
Month 3: Maximum score for Nausea	sed3_max		On a scale 0-10
Month 3: Maximum score for Dizziness	sed4_max		On a scale 0-10
Month 3: Maximum score for Decrease in Appetite	sed5_max		On a scale 0-10
Month 3: Maximum score for fatigue	sed6_max		On a scale 0-10
Month 3: Maximum score for abnormal sweating	sed7_max		On a scale 0-10
Month 3: Maximum score for trouble sleeping	sed8_max		On a scale 0-10
Month 3: Maximum score for mood swings	sed9_max		On a scale 0-10
Month 3: Maximum score for trouble concentrating	sed10_max		On a scale 0-10
Month 3: Maximum score for Hot Flashes	sed11_max		On a scale 0-10
Month 3: Maximum score for Deepening of voice	sed12_max		On a scale 0-10
Month 3: Maximum score for unwanted weight gain	sed13_max		On a scale 0-10

LABEL	NAME	ELEMENTS	COMMENTS
Month 3: Maximum score for acne type rash	sed14_max		On a scale 0-10
Month 3: Maximum score for Swelling in Hands or Feet	sed15_max		On a scale 0-10
Month 3: Maximum score for undesirable hair growth	sed16_max		On a scale 0-10
Month 3: Maximum score for undesirable scalp growth	sed17_max		On a scale 0-10
Month 6: Maximum score for Stomach Pain or Cramps	sed1_max6		On a scale 0-10
Month 6: Maximum score for Diarrhea	sed2_max6		On a scale 0-10
Month 6: Maximum score for Nausea	sed3_max6		On a scale 0-10
Month 6: Maximum score for Dizziness	sed4_max6		On a scale 0-10
Month 6: Maximum score for Decrease in Appetite	sed5_max6		On a scale 0-10
Month 6: Maximum score for fatigue	sed6_max6		On a scale 0-10
Month 6: Maximum score for abnormal sweating	sed7_max6		On a scale 0-10
Month 6: Maximum score for trouble sleeping	sed8_max6		On a scale 0-10
Month 6: Maximum score for mood swings	sed9_max6		On a scale 0-10
Month 6: Maximum score for trouble concentrating	sed10_max6		On a scale 0-10
Month 6: Maximum score for Hot Flashes	sed11_max6		On a scale 0-10
Month 6: score for Deepening of voice	sed12_max6		On a scale 0-10
Month 6: Maximum score for unwanted weight gain	sed13_max6		On a scale 0-10
Month 6: Maximum score for acne type rash	sed14_max6		On a scale 0-10
Month 6: Maximum score for Swelling in Hands or Feet	sed15_max6		On a scale 0-10
Month 6: Maximum score for undesirable hair growth	sed16_max6		On a scale 0-10
Month 6: Maximum score for undesirable scalp growth	sed17_max6		On a scale 0-10