

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-D14-Dataset.csv (supplemental3)

Description: Dataset NCT01573442-D14-Dataset.csv (supplemental3) is one of 14 datasets associated with PubMed ID 32372176. This dataset contains information that will allow you to reproduce the Supplemental Table 3.

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-D14-Dataset.csv (supplemental3) Data Dictionary:

LABEL	NAME	ELEMENTS	COMMENTS
Patient ID	patref		
Arm	arm	Testosterone, Placebo	
Month 3: Hot Flashes?	q01_3_form	Yes, No	
Month 3: Night Sweats?	q02_3_form	Yes, No	
Month 3: Sweating?	q03_3_form	Yes, No	
Month 3: Dissatisfaction with Personal Life?	q04_3_form	Yes, No	
Month 3: Anxious or Nervous?	q05_3_form	Yes, No	
Month 3: Poor Memory?	q06_3_form	Yes, No	
Month 3: Accomplishing Less?	q07_3_form	Yes, No	
Month 3: Depressed?	q08_3_form	Yes, No	
Month 3: Impatient with other people?	q09_3_form	Yes, No	
Baseline: Wanting to be Alone?	q10_0_form	Yes, No	
Baseline: Flatulence or Gas Pains?	q11_0_form	Yes, No	
Month 3: Aching muscles or joints?	q12_3_form	Yes, No	
Month 3: Tired or Worn out?	q13_3_form	Yes, No	
Month 3: Difficulty Sleeping?	q14_3_form	Yes, No	
Month 3: Aches in back of head or neck?	q15_3_form	Yes, No	
Month 3: Decrease in physical strength?	q16_3_form	Yes, No	
Month 3: Decrease in stamina?	q17_3_form	Yes, No	
Month 3: Lack of energy?	q18_3_form	Yes, No	

LABEL	NAME	ELEMENTS	COMMENTS
Month 3: Dry Skin?	q19_3_form	Yes, No	
Month 3: Weight Gain?	q20_3_form	Yes, No	
Month 3: Increased Facial Hair?	q21_3_form	Yes, No	
Month 3: Changes in appearance, texture or tone of your skin?	q22_3_form	Yes, No	
Month 3: Bloating?	q23_3_form	Yes, No	
Month 3: Low Backache	q24_3_form	Yes, No	
Month 3: Frequent Urination?	q25_3_form	Yes, No	
Month 3: Involuntary urination when laughing or coughing?	q26_3_form	Yes, No	
Month 3: Decreased Sex Drive?	q27_3_form	Yes, No	
Month 3: Vaginal Dryness?	q28_3_form	Yes, No	
Month 3: Avoiding Intimacy?	q29_3_form	Yes, No	
Month 3: Breast Pain or Tenderness?	q30_3_form	Yes, No	
Month 3: Vaginal Bleeding or Spotting?	q31_3_form	Yes, No	
Month 3: Leg Pains or Cramps?	q32_3_form	Yes, No	
Baseline: Hot Flashes?	q01_0_form	Yes, No	
Baseline: Night Sweats?	q02_0_form	Yes, No	
Baseline: Sweating?	q03_0_form	Yes, No	
Baseline: Dissatisfaction with Personal Life?	q04_0_form	Yes, No	
Baseline: Anxious or Nervous?	q05_0_form	Yes, No	
Baseline: Poor Memory?	q06_0_form	Yes, No	
Baseline: Accomplishing Less?	q07_0_form	Yes, No	
Baseline: Depressed?	q08_0_form	Yes, No	
Baseline: Impatient with other people?	q09_0_form	Yes, No	
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