

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-D11-Dataset.csv (subcut)

Description: Dataset NCT01573442-D11-Dataset.csv (subcut) is one of 14 datasets associated with PubMed ID 32372176. This dataset contains information on 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-D11-Dataset.csv (subcut) Data Dictionary:

LABEL	NAME	ELEMENTS	COMMENTS
Patient identifier	patref		
Month 3: BPI Average Pain	BPI4_3	1, 4, 2, NA, 3, 5, 0, 10, 7, 6	On a scale 0-10
Aromatase Duration	DUR_AROM	6-12 months, >12 months, <6 months	
Weight (kg)	WEIGHT		
Body Mass Index (kg/m^2)	BMI		
ECOG PS	ECOGPS	0, 1, 2	
Arm	ARM	Placebo, Testosterone	
Baseline Average Pain Score	bas_pain		On a scale 0-10
Change in BPI Average Pain from baseline to month 1	bpi4_10		
Baseline: Wanting to be Alone?	q10_0_form	Yes, No	
Baseline: Flatulence or Gas Pains?	q11_0_form	Yes, No	
Month 3: Changes in appearance, texture or tone of your skin?	q22_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	
Baseline: Hot Flashes?	q01_0_form	Yes, No	
Baseline: Night Sweats?	q02_0_form	Yes, No	

LABEL	NAME	ELEMENTS	COMMENTS
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	
Baseline: Aching muscles or joints?	q12_0_form	Yes, No	
Baseline: Tired or Worn out?	q13_0_form	Yes, No	
Baseline: Difficulty Sleeping?	q14_0_form	Yes, No	
Baseline: Aches in back of head or neck?	q15_0_form	Yes, No	
Baseline: Decrease in physical strength?	q16_0_form	Yes, No	
Baseline: Decrease in stamina?	q17_0_form	Yes, No	
Baseline: Lack of energy?	q18_0_form	Yes, No	
Baseline: Dry Skin?	q19_0_form	Yes, No	
Baseline: Weight Gain?	q20_0_form	Yes, No	
Baseline: Increased Facial Hair?	q21_0_form	Yes, No	
Baseline: Changes in appearance, texture or tone of your skin?	q22_0_form	Yes, No	
Baseline: Bloating?	q23_0_form	Yes, No	
Baseline: Low Backache	q24_0_form	Yes, No	
Baseline: Frequent Urination?	q25_0_form	Yes, No	
Baseline: Involuntary urination when laughing or coughing?	q26_0_form	Yes, No	
Baseline: Decreased Sex Drive?	q27_0_form	Yes, No	
Baseline: Vaginal Dryness?	q28_0_form	Yes, No	
Baseline: Avoiding Intimacy?	q29_0_form	Yes, No	
Baseline: Breast Pain or Tenderness?	q30_0_form	Yes, No	
Baseline: Vaginal Bleeding or Spotting?	q31_0_form	Yes, No	
Baseline: Leg Pains or Cramps?	q32_0_form	Yes, No	

LABEL	NAME	ELEMENTS	COMMENTS
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
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
Pct of Baseline HF Score at Week 8	pscore		
Pct of Baseline HF Freq at Week 8	pfreq		

LABEL	NAME	ELEMENTS	COMMENTS
Race	race	White, Not reported or unknown	
Ethnicity	ethn	Non-Hispanic, Not reported or unknown, Hispanic	