

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-D8-Dataset.csv (supplemental2)

Description: Dataset NCT01573442-D8-Dataset.csv (supplemental2) is one of 14 datasets associated with PubMed ID 32372176. This dataset contains data presented in supplemental table S2.

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-D8-Dataset.csv (supplemental2) Data Dictionary:

LABEL	NAME	ELEMENTS	COMMENTS
Patient ID	patref		
Baseline: How bothered are you by Hot Flashes?	Q01A_0		On a scale 0-6
Baseline: How bothered are you by Night Sweats?	Q02A_0		On a scale 0-6
Baseline: How bothered are you by Sweating?	Q03A_0		On a scale 0-6
Baseline: How bothered are you by Dissatisfaction with Personal Life?	Q04A_0		On a scale 0-6
Baseline: How bothered are you by feeling Anxious or Nervous?	Q05A_0		On a scale 0-6
Baseline: How bothered are you by poor Memory?	Q06A_0		On a scale 0-6
Baseline: How bothered are you by Accomplishing Less?	Q07A_0		On a scale 0-6
Baseline: How bothered are you by feeling Depressed?	Q08A_0		On a scale 0-6
Baseline: How bothered are you by feeling impatient with other people?	Q09A_0		On a scale 0-6
Baseline: How bothered are you by Wanting to be Alone?	Q10A_0		On a scale 0-6
Baseline: How bothered are you by flatulence or gas pains?	Q11A_0		On a scale 0-6
Baseline: How bothered are you by aching muscles or joints?	Q12A_0		On a scale 0-6
Baseline: How bothered are you by feeling tired or worn out?	Q13A_0		On a scale 0-6

LABEL	NAME	ELEMENTS	COMMENTS
Baseline: How bothered are you by difficulty sleeping?	Q14A_0		On a scale 0-6
Baseline: How bothered are you by aches in back of head or neck?	Q15A_0		On a scale 0-6
Baseline: How bothered are you by decrease in physical strength?	Q16A_0		On a scale 0-6
Baseline: How bothered are you by decrease in stamina?	Q17A_0		On a scale 0-6
Baseline: How bothered are you by lack of energy?	Q18A_0		On a scale 0-6
Baseline: How bothered are you by dry skin?	Q19A_0		On a scale 0-6
Baseline: How bothered are you by weight gain?	Q20A_0		On a scale 0-6
Baseline: How bothered are you by increased facial hair?	Q21A_0		On a scale 0-6
Baseline: How bothered are you by changes in appearance, texture or tone of your skin?	Q22A_0		On a scale 0-6
Baseline: How bothered are you by feeling bloated?	Q23A_0		On a scale 0-6
Baseline: How bothered are you by low backache?	Q24A_0		On a scale 0-6
Baseline: How bothered are you by frequent urination?	Q25A_0		On a scale 0-6
Baseline: How bothered are you by involuntary urination when laughing or coughing?	Q26A_0		On a scale 0-6
Baseline: How bothered are you by decreased sex drive?	Q27A_0		On a scale 0-6
Baseline: How bothered are you by vaginal dryness?	Q28A_0		On a scale 0-6
Baseline: How bothered are you by avoiding intimacy?	Q29A_0		On a scale 0-6
Baseline: How bothered are you by breast pain or tenderness?	Q30A_0		On a scale 0-6
Baseline: How bothered are you by vaginal bleeding or spotting?	Q31A_0		On a scale 0-6
Baseline: How bothered are you by leg pain or cramps?	Q32A_0		On a scale 0-6
Arm	arm	Testosterone, Placebo	

LABEL	NAME	ELEMENTS	COMMENTS
Baseline: Wanting to be Alone?	q10_0_form	Yes, No	
Baseline: Flatulence or Gas Pains?	q11_0_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	
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	