

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-D6-Dataset.csv (qol3)

Description: Dataset NCT01573442-D6-Dataset.csv (qol3) is one of 14 datasets associated with PubMed ID 32372176. This dataset contains data on the HFRDIS and POMS QoL analyses.

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-D6-Dataset.csv (qol3) Data Dictionary:

LABEL	NAME	ELEMENTS	COMMENTS
Patient ID	patref		
Baseline: Work	HFRDIS01_0		On a scale 0-10
Baseline: Social Activities	HFRDIS02_0		On a scale 0-10
Baseline: Leisure Activities	HFRDIS03_0		On a scale 0-10
Baseline: Sleep	HFRDIS04_0		On a scale 0-10
Baseline: Mood	HFRDIS05_0		On a scale 0-10
Baseline: Concentration	HFRDIS06_0		On a scale 0-10
Baseline: Relations with others	HFRDIS07_0		On a scale 0-10
Baseline: Sexuality	HFRDIS08_0		On a scale 0-10
Baseline: Enjoyment of Life	HFRDIS09_0		On a scale 0-10
Baseline: Overall Quality of Life	HFRDIS10_0		On a scale 0-10
Month 3: Work	HFRDIS01_3		On a scale 0-10
Month 3: Social Activities	HFRDIS02_3		On a scale 0-10
Month 3: Leisure Activities	HFRDIS03_3		On a scale 0-10
Month 3: Sleep	HFRDIS04_3		On a scale 0-10
Month 3: Mood	HFRDIS05_3		On a scale 0-10
Month 3: Concentration	HFRDIS06_3		On a scale 0-10
Month 3: Relations with others	HFRDIS07_3		On a scale 0-10
Month 3: Sexuality	HFRDIS08_3		On a scale 0-10
Month 3: Enjoyment of Life	HFRDIS09_3		On a scale 0-10
Month 3: Overall Quality of Life	HFRDIS10_3		On a scale 0-10
Month 3: Tense	POMS01_3		On a scale 0-4
Month 3: Angry	POMS02_3		On a scale 0-4
Month 3: Worn Out	POMS03_3		On a scale 0-4
Month 3: Lively	POMS04_3		On a scale 0-4

Month 3: Confused	POMS05_3		On a scale 0-4
Month 3: Shaky	POMS06_3		On a scale 0-4
Month 3: Sad	POMS07_3		On a scale 0-4
Month 3: Active	POMS08_3		On a scale 0-4
Month 3: Grouchy	POMS09_3		On a scale 0-4
Month 3 Energetic	POMS10_3		On a scale 0-4

LABEL	NAME	ELEMENTS	COMMENTS
Month 3: Unworthy	POMS11_3		On a scale 0-4
Month 3: Uneasy	POMS12_3		On a scale 0-4
Month 3: Fatigued	POMS13_3		On a scale 0-4
Month 3: Annoyed	POMS14_3		On a scale 0-4
Month 3: Discouraged	POMS15_3		On a scale 0-4
Month 3: Nervous	POMS16_3		On a scale 0-4
Month 3: Lonely	POMS17_3		On a scale 0-4
Month 3: Muddled	POMS18_3		On a scale 0-4
Month 3: Exhausted	POMS19_3		On a scale 0-4
Month 3: Anxious	POMS20_3		On a scale 0-4
Month 3: Gloomy	POMS21_3		On a scale 0-4
Month 3: Sluggish	POMS22_3		On a scale 0-4
Month 3: Weary	POMS23_3		On a scale 0-4
Month 3: Bewildered	POMS24_3		On a scale 0-4
Month 3: Furious	POMS25_3		On a scale 0-4
Month 3: Efficient	POMS26_3		On a scale 0-4
Month 3: Full of Pep	POMS27_3		On a scale 0-4
Month 3: Bad-tempered	POMS28_3		On a scale 0-4
Month 3: Forgetful	POMS29_3		On a scale 0-4
Month 3: Vigorous	POMS30_3		On a scale 0-4
Arm	arm	Testosterone, Placebo	