NCCTG-N10C1

Vaginal DHEA for Vaginal Symptoms: A Phase III Randomized, Double Blind, Placebo- Controlled Trial

ClinicalTrial.gov Identifier: NCT01376349

Study Background

Trial Description

RATIONALE: Dehydroepiandrosterone (DHEA) may help relieve vaginal symptoms in female cancer survivors. PURPOSE: This randomized phase III trial studies DHEA to see how well it works compared to placebo in treating postmenopausal cancer survivors with vaginal symptoms.

Arms:

Arm I low dose DHEA: (Experimental): Participants apply a low dose (3.25 mg) of vaginal prasterone (dehydroepiandrosterone [DHEA]) gel once daily (QD), at bed time, for 12 weeks. Treatment continues until unacceptable adverse events or patient refusal to continue participation on the study.

Arm II high dose DHEA: (Experimental): Participants apply a high dose (6.5 mg) of vaginal DHEA gel QD, at bed time, for 12 weeks. Treatment continues until unacceptable adverse events or patient refusal to continue participation on the study.

Arm III placebo: (Placebo Comparator): Participants apply a vaginal placebo gel QD, at bed time, for 12 weeks. There is an Optional Continuation Phase (for placebo arm only): Participants apply a high dose of vaginal DHEA gel QD, at bed time, for 12 weeks. Treatment continues until unacceptable adverse events or patient refusal to continue participation on the study.

Objectives:

- Primary Goal:
  - To determine the effectiveness of two doses of daily vaginal prasterone (dehydroepiandrosterone [DHEA]) versus placebo for alleviation of the most bothersome vaginal symptom (vaginal dryness or dyspareunia) over 12 weeks.
- Exploratory Goals:
  - To evaluate any toxicities arising from DHEA in this patient population. (Exploratory)
  - To evaluate the impact of vaginal DHEA on negative sexual thoughts, sexual function and urologic symptoms. (Exploratory)

  - To explore the role of psychologic (mood, stress), physical (demographics and treatment variables) and situational factors (partner variables and fatigue) as predictors of vaginal dryness and performance outcomes at baseline and at various endpoints throughout the study. (Exploratory)
  - To explore the characteristics of vaginal atrophy and the relationship between vaginal atrophy and quality-of-life questionnaire responses and exposure to hormonal therapy (tamoxifen, exemestane, anastrozole, or letrozole). (Exploratory)
  - To examine the effects of the use of open-label vaginal DHEA gel over 8 weeks in women completing the placebo gel arm of the randomized trial. (Exploratory)
- Correlative Research Goals:
  - To evaluate the impact of vaginal DHEA on maturation index and pH (select institutions).
  - To evaluate the impact of vaginal DHEA on sex steroid concentrations (estradiol, free testosterone, estrone, and DHEA-S) and markers of bone turnover (osteocalcin and bone alkaline phosphatase). (Correlative)
  - As part of ongoing research for NCCTG Cancer Control studies, we are banking blood products for future studies. (Correlative)
- OUTLINE: This is a multicenter study. Patients are stratified according to current tamoxifen therapy (yes vs no), concurrent aromatase inhibitor use (anastrozole/letrozole vs exemestane vs none), hysterectomy (yes vs no), and cigarette smoking (current vs past vs never). Patients are randomized to 1 of 3 treatment arms, patients receive low dose vaginal DHEA, high dose vaginal DHEA or vaginal placebo gel.
- Participants may complete the Profile of Mood States (POMS), the Perceived Stress Scale (PSS), the Fatigue: Vitality subscale of the SF-36, the Vaginal Symptom Quality Questionnaire, the DHEA Side Effect Questionnaire, the Female Sexual Function Index (FSFI), the Sexually Related Intrusive Thoughts - ITS, Impact of Treatment Scale, the Urogenital Atrophy Questionnaire, and the Subject Global Impression of Change at baseline and periodically during study.

Study Milestones:

Start date: July 2011

Primary Completion Date: August 2013

Publication Information:

Analysis Type: Primary

Pubmed ID: 28921241

Citation: Support Care Cancer. 2018 Feb;26(2):643-650. doi: 10.1007/s00520-017-3878-2. Epub 2017 Sep 18.

Associated Datasets: NCT01376349-D1-Dataset.csv (consort), NCT01376349-D2-Dataset.csv (figure2), NCT01376349-D3-Dataset.csv (table1), NCT01376349-D4-Dataset.csv (table2), NCT01376349-D5-Dataset.csv (table3), NCT01376349-D6-Dataset.csv (AE)

Dataset Information:

Dataset Name: NCT01376349-D6-Dataset.csv (AE)

Description: Dataset NCT01376349-D6-Dataset.csv (AE) is one of 6 datasets associated with PubMed ID 28921241. This dataset contains all reported adverse events during 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).

Missing indicates the data was not available or not collected.

NCT01376349-D6-Dataset.csv (AE) Data Dictionary:

LABEL	NAME	elements	comments
Patient Reference	PATREF		De-identified patient reference
Cycle	CYCLE		Cycle of treatment
CTCAE v4 grade	GRADE	1, 2, 3, 4	
Toxicity	TOXICITY		
Relationship to treatment	REL_SMED	UNLIKELY, POSSIBLE, PROBABLE, DEFINITE, NOT RELATED	