Alliance Public Study Result Summary
In Symptom Intervention
Study Number N10C1

What this study is about

A cancer study that looked at three different treatments to improve vaginal symptoms of dryness or pain with intercourse in postmenopausal women who had a history of either breast or gynecologic cancer.

The full title of this study is: Vaginal DHEA for Vaginal Symptoms: A Phase III Randomized, Double Blind, Placebo- Controlled Trial

Why the study was done

This study was done to compare the effects, good and/or bad, of three different treatments (3.25 mg of DHEA daily, 6.5 mg of DHEA daily or a plain moisturizer daily) for vaginal dryness and overall sexual health in postmenopausal women with a history of breast or gynecologic cancer. Overall, sexual health was measured by sexual desire, arousal, lubrication, orgasm, satisfaction, and pain with intercourse. DHEA is a steroid called dehydroepiandrosterone.

Study results

These results are for postmenopausal women with a history of breast or gynecologic cancer who had completed chemotherapy and radiation, who had no evidence of current disease and who reported at least moderate vaginal dryness or pain with intercourse.

Dryness or pain reported by the patient

- The study found that all women reported similar improvement in either dryness or pain with intercourse in all treatment arms after 12 weeks of treatment
- The study found that women who received the larger dose of DHEA had an improvement in symptoms more quickly and a significant difference after 8 weeks of treatment.

Overall sexual health reported by the patient

- The study found that women who received the larger dose of DHEA reported significantly better overall sexual health as measured by sexual desire, arousal, lubrication, orgasm, satisfaction, and pain with intercourse.
- The study found that all three groups of women reported better sexual health after 12 weeks of treatment.

Side effects reported by the doctor and patient

- The study found that doctors reported no significant differences in side effects among the three arms.
- The study found that the patients in both DHEA arms reported significant worsening voice changes and headaches than patients in the plain moisturizer arm.

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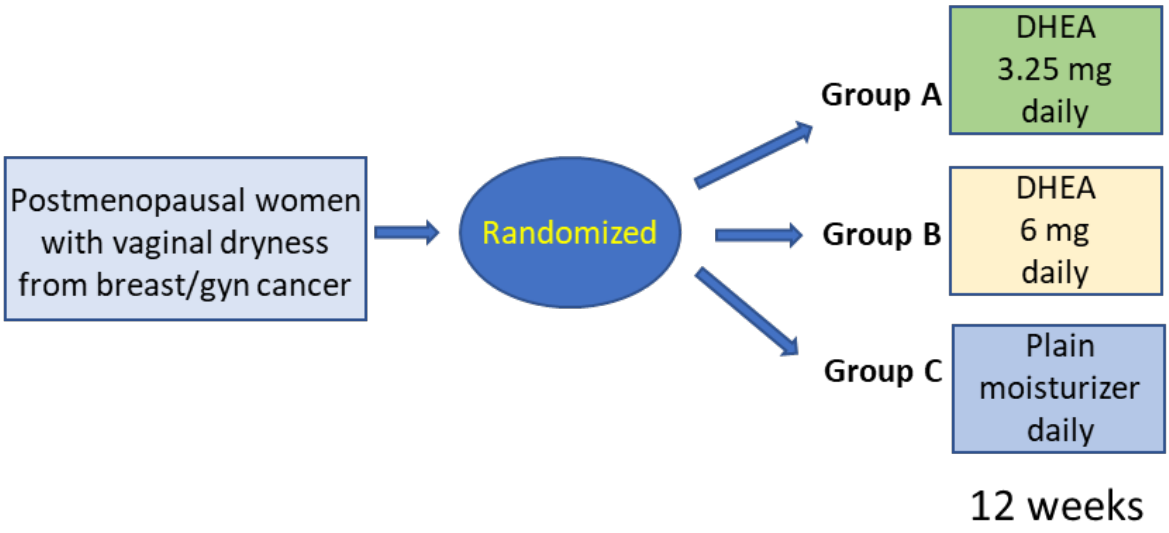
What the results mean

Plain moisturizer and DHEA improved vaginal symptoms at 12 weeks. However, vaginal DHEA, 6.5 mg, significantly improved sexual health. Vaginal DHEA warrants further investigation in women with a history of cancer.

How the study worked

Here's a picture that explains how patients were placed into this study.



Patients were randomized to Group A (3.25mg DHEA daily), Group B (6.0mg DHEA daily) or Group C (plain moisturizer daily) and followed for 12 weeks.

Abbreviations
Randomization is the process by which patients are assigned by chance to separate groups.
DHEA is a dehydroepiandrosterone gel that the patient inserts into her vagina before bed every day.
Plain moisturizer does not contain medicine and looks the same as the drug and is inserted into the vagina before bed every day.

When did the study start and end? The study started in July 2011. All patients were enrolled by April 2013.

How many patients joined? Four hundred sixty-four women agreed to be in this study.

Talk to your doctor if you want more information about this study.

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Scientific publications about this study

Details about the study can be found in these articles:

- Barton DL, Sloan JA, Shuster LT, Gill P, Griffin P, Flynn K, Terstriep SA, Rana FN, Dockter T, Atherton PJ, Tsai M, Sturtz K, Lafky JM, Riepl M, Thielen J, Loprinzi CL. Evaluating the efficacy of vaginal dehydroepiandosterone for vaginal symptoms in postmenopausal cancer survivors: NCCTG N10C1 (Alliance). Support Care Cancer. 2018 Feb;26(2):643-650. doi: 10.1007/s00520-017-3878-2. Epub 2017 Sep 18. PMID: 28921241; PMCID: PMC5754227.

To learn about this trial, visit the ClinicalTrials.gov website at:

https://clinicaltrials.gov/ct2/show/NCT01376349

This study was sponsored by the Alliance for Clinical Trials in Oncology – a national clinical trial network group that runs large cancer clinical trials. The Alliance is supported by the National Cancer Institute (NCI) and brings researchers together to develop better treatments for cancers. More information about the Alliance is at www.AllianceNCTN.org.

This summary lists what is known about this research study as of July 2021

We thank the people who joined this study and made it possible.
We do research to try to learn the best ways to help patients.
The people who joined this study helped us to do that.

Thank you for your interest in learning more about cancer research advances.