Study Suggests Testosterone May Help Ease Menopausal Symptoms Without Increasing Breast Cancer Risk

TOPIC: *Diagnosis and Menopausal Symptoms*

TAGS: *Managing Hot Flashes, Managing Sleep Problems, and Postmenopausal*

Early results from a study suggest that testosterone implanted under the skin (subcutaneously) as a pellet about every 3 months helped ease menopausal symptoms without raising a woman's risk of breast cancer.

The results were published online on Sept. 3, 2013 by the journal *Maturitas*. Read the abstract of "Reduced breast cancer incidence in women treated with subcutaneous testosterone, or testosterone with anastrozole: A prospective, observational study."

Menopausal symptoms such as hot flashes and night sweats can dramatically reduce quality of life for some women. Some women use hormone replacement therapy (HRT) to ease these symptoms. But research has shown that HRT increases breast cancer risk in women who haven't been diagnosed. HRT also increases the risk of breast cancer coming back (recurrence) in women who have been diagnosed with the disease. HRT is not recommended for women who've been diagnosed with breast cancer. Undiagnosed women who have severe menopausal symptoms need to weigh the benefits of HRT against its risks.

Earlier research has shown that giving testosterone subcutaneously may ease several menopausal symptoms, including hot flashes, sleep problems, irritability, and fatigue. While testosterone is considered a male hormone because men have much higher levels, women do have testosterone. In men, testosterone is made by the testes. In women, the hormone is made by the ovaries and adrenal glands. Testosterone helps maintain:

- bone density
- fat distribution
- muscle strength and mass
- red blood cell production
- sex drive
- sperm production (in men only)

In women, the enzyme aromatase converts some testosterone to estradiol, a type of estrogen. Because HRT has been found to increase breast cancer risk, doctors believe that estradiol converted from testosterone could affect breast cancer risk.

In this study, called the Testosterone Implant Breast Cancer Prevention Study, the researchers wanted to see if using testosterone instead of the hormones in HRT -- estrogen and progesterone -- to treat menopausal symptoms would increase the risk of breast cancer.

While these results are promising, they are still EARLY results. The researchers are continuing the study and plan to report more results as they're collected. Also, testosterone pellets are not approved by the U.S. Food and Drug Administration to treat menopausal symptoms and aren't commonly used for this purpose.

If you're having troubling menopausal symptoms, talk to your doctor about all your options. Ask how you can minimize your risk of breast cancer AND relieve your symptoms. Be sure to discuss the pros and cons of currently available HRT options. Research suggests that estrogen-only HRT increases breast cancer risk less than combination HRT, which contains estrogen and progesterone. If you do decide to take HRT, ask if you can take a lower-dose formula and try to take it for the shortest time possible. You also may want to ask your doctor about vaginal or transdermal HRT.

Some complementary and holistic medicine techniques have been shown to ease hot flashes, including exercise, yoga, cognitive behavioral therapy, and acupuncture.

You can learn more about menopause and steps you can take to ease bothersome symptoms in the Breastcancer.org Managing Menopausal Symptoms pages.

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Testosterone in Treating Postmenopausal Patients With Arthralgia Caused by Adjuvant Aromatase Inhibitor Treatment

This study is currently recruiting participants. (see Contacts and Locations)
Verified June 2016 by Alliance for Clinical Trials in Oncology

Sponsor:
Alliance for Clinical Trials in Oncology

Collaborator:
National Cancer Institute (NCI)

Information provided by (Responsible Party):
Alliance for Clinical Trials in Oncology

ClinicalTrials.gov Identifier:
NCT01573442

First received: April 6, 2012
Last updated: June 13, 2016
Last verified: June 2016
History of Changes

Full Text View | Tabular View | No Study Results Posted | Disclaimer | How to Read a Study Record

Purpose

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.

Condition	Intervention	Phase
Arthralgia Breast Cancer Hot Flashes Musculoskeletal Complications Sexual Dysfunction	Drug: testosterone Other: placebo Drug: anastrozole	Phase 3

Study Type: Interventional
Study Design: Allocation: Randomized
Intervention Model: Parallel Assignment
Masking: Double Blind (Subject, Investigator)
Primary Purpose: Supportive Care

Official Title: Randomized Double-Blind Placebo Controlled Study of Subcutaneous Testosterone in the Adjuvant Treatment of Postmenopausal Women With Aromatase Inhibitor Induced Arthralgias

Resource links provided by NLM:

Genetics Home Reference related topics: breast cancer

MedlinePlus related topics: Cancer

Drug Information available for: Testosterone propionate Methyltestosterone Testosterone cypionate Testosterone Testosterone enanthate Testosterone undecanoate Anastrozole

U.S. FDA Resources

Further study details as provided by Alliance for Clinical Trials in Oncology:

Primary Outcome Measures:

- Intra-patient change in joint pain at 3 months from baseline as measured by item #3 (average) of the Brief Pain Inventory [Time Frame: Up to 3 months] [Designated as safety issue: No]
- Proportion of women with changes in pain at least 10 points on a converted 0-100 scale at 3 months from baseline [Time Frame: Up to 3 months] [Designated as safety issue: No]

2. Receiving anastrozole (1mg) or letrozole (2.5 mg) orally once a day, for ≥ 21 days prior to registration and plan to continue it throughout the duration of study
3. Body Mass Index (BMI) between 18 and 35 kg/m^2
4. Women who have undergone a total mastectomy or breast conserving surgery for primary breast cancer +/-chemo, +/-radiotherapy.
5. Must have BOTH ER and PR receptor-positive tumors and BOTH must be ≥20% positive. Alternatively, if ER and PR are determined by Allred score, the score needs to be 6 or higher
6. Women who are postmenopausal by surgery, radiotherapy or presence of natural amenorrhea ≥ 12 months
7. ≥ 5/10 arthralgia (in hands, wrist, knees, or hips) while being treated with anastrozole or letrozole which is felt by the patient to be caused by their aromatase inhibitor as defined in the protocol. Note: Patients may, or may not, be taking non-opiod analgesics
8. Ability to complete questionnaire(s) by themselves or with assistance
9. ECOG Performance Status (PS) 0, 1 or 2
10. Willing to provide informed written consent
11. Willing to return to an Alliance enrolling institution for follow-up
12. Willing to provide blood samples for correlative research purposes
13. Laboratory values prior to registration as defined in the protocol:
    a. Creatinine ≤1.5 x ULN
    b. Hemoglobin > 11 g/dL
    c. WBC > 3.0
    d. Platelet Count > 100,000
    e. SGOT (AST) ≤ 1.5 x ULN

Exclusion Criteria:

1. Presence of residual or recurrent cancer (locally or metastatic)
2. Diabetes mellitus or glucose intolerance, defined as a fasting glucose >125 mg/dL
3. History of coronary artery disease (angina or myocardial infarction)
4. Patients on hormone replacement therapy (HRT) ≤ 4 weeks prior to registration. This includes the use of vaginal estrogen therapy.
5. Known hypersensitivity to any component of testosterone.
6. Prolonged systemic corticosteroid treatment, except for topical applications (e.g. for rash), inhaled sprays (e.g. for obstructive airway diseases), eye drops or local insertion (e.g. intra-articular). Note: Short duration (< 2 weeks) of systemic corticosteroids is allowed (e.g. for chronic obstructive pulmonary disease) but not within 30 days prior to registration.
7. Receiving any other investigational agent
8. History of a deep venous thrombosis or a thromboembolism
9. Concurrent use of the aromatase inhibitor exemestane, as it is structurally similar to an androgen
10. Concurrent radiation therapy or chemotherapy
11. Current or planned use of cyclosporine, anticoagulants, oxphenbutazone, insulin, oral or injectable vitamin D doses over 4,000IU/day, or tamoxifen

▶ Contacts and Locations

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the Contacts provided below. For general information, see Learn About Clinical Studies.

Please refer to this study by its ClinicalTrials.gov identifier: NCT01573442

Contacts

Contact: Charles Loprinzi, MD (507) 284-4565

Show 270 Study Locations

Sponsors and Collaborators

Alliance for Clinical Trials in Oncology

National Cancer Institute (NCI)

Investigators

Study Chair: Charles Loprinzi, MD Mayo Clinic

▶ More Information