MADISON MEDICAL COMPOUNDING PHARMACY

Phone 601-707-7545
Fax 601-856-8985
www.mmcpharmacy.com

Thank you for entrusting in the compounding services at Madison Medical Compounding Pharmacy to help meet the unique medication needs of your patients. We are excited to share our monthly newsletter with you and look forward to working with you. Please don't hesitate to let us know how we can assist you and your practice.

LeAnn Chambers, Pharm.D. and Matthew Chambers, Pharm.D.

Hormonal, Metabolic, and Endometrial Safety of Testosterone Vaginal Cream versus Estrogens for the Treatment of Vulvovaginal Atrophy in Postmenopausal Women: a Randomized, Placebo-Controlled Study

The aim of the study was to evaluate the laboratory and endometrial safety of topical testosterone versus topical estrogen for the treatment of vaginal atrophy in postmenopausal women. This was a randomized, placebo-controlled trial of 60 postmenopausal women aged 40 to 70 years at the Menopause Clinic of CAISM UNICAMP (Brazil). Women were randomized to one of the following groups and received treatment 3 times a week for 12 weeks: 1) testosterone propionate vaginal: one vaginal applicator with 1 gm of cream per application containing 300 mcg/gm testosterone propionate prepared in emollient cream; 2) conjugated estrogens: one vaginal applicator with 1 gm of cream per application containing 0.625 mg conjugated estrogens (Premarin®, Wyeth); or 3) glycerin lubricant (placebo): one vaginal applicator with 3m g of gel per application (K-Y Gel, Johnson & Johnson).

Hormonal laboratory values of follicle-stimulating hormone, luteinizing hormone, estradiol, estrone, androstenedione, total testosterone, free testosterone, dehydroepiandrosterone (DHEA), DHEA sulfate, and sex hormone-binding globulin were assessed at baseline and at 6 and 12 weeks. Metabolic laboratory values of total cholesterol, high-density lipoprotein cholesterol, low-density lipoprotein cholesterol, triglycerides, aspartate aminotransferase, alanine aminotransferase, alkaline phosphatase, and gamma-glutamyl transpeptidase were also assessed at baseline and at 6 and 12 weeks. Endometrial safety was assessed using ultrasonography at baseline and at 12 weeks. After 12 weeks of treatment, there were no significant differences in hormonal or metabolic laboratory values among all three groups. Two participants in the estrogen group had increased serum estradiol after 12 weeks of treatment. No change in endometrial thickening was reported in all three groups.

The authors concluded that 12 weeks of treatment with topical testosterone or estrogen in postmenopausal women with symptoms of vaginal atrophy demonstrated laboratory and endometrial safety when compared with placebo.

Menopause. 2018 Jun;25(6):641-647.

Vaginal Testosterone Cream vs Estradiol Vaginal Ring for Vaginal Dryness or Decreased Libido in Women Receiving Aromatase Inhibitors for Early-Stage Breast Cancer

The use of aromatase inhibitors (AI such as anastrozole, letrozole, and exemestane) for the treatment of breast cancer is associated with significant urogenital atrophy, affecting quality of life and compliance with therapy. A randomized clinical trial evaluated the safety of intravaginal testosterone cream (IVT) or an estradiol-releasing vaginal ring (7.5 microgram/day) in postmenopausal women with hormone receptor-positive stage I to III breast cancer taking AIs with self-reported vaginal dryness, dyspareunia, or decreased libido. Intervention was considered unsafe if more than 25% of patients had persistent elevation in estradiol (E2), defined as E2 greater than 10 pg/mL and at least 10 pg/mL above baseline after treatment initiation on 2 consecutive tests at least 2 weeks apart.

Women were randomized to receive IVT (micronized testosterone 1% in a cream base, 0.5 gm cream vaginally each night for two weeks, then 3 times a week for total of 12 weeks of treatment) or an estradiol vaginal ring (Estring® 2mg ring inserted vaginally once every 12 weeks). Estradiol was measured at baseline and weeks 4 and 12 and follicle-stimulating hormone levels were measured at baseline and week 4. Gynecologic examinations and sexual quality-of-life questionnaires were completed at baseline and week 12.

The primary objective was to evaluate the safety of IVT or an estradiol vaginal ring in patients with early-stage BC receiving an AI; secondary objectives included evaluation of adverse events, changes in sexual quality of life, changes in vaginal atrophy, and comparison of E2 levels.

Overall, 76 women signed consent (mean [range] age, 56 [37-78] years), and 69 completed 12 weeks of treatment. The trial concluded that in postmenopausal women with early-stage breast cancer receiving AIs, treatment with an estradiol vaginal ring or intravaginal testosterone over 12 weeks met the primary safety endpoint. Baseline elevation in E2 was common. Vaginal atrophy, sexual interest, and sexual dysfunction were improved.

JAMA Oncol. 2017 Mar 1;3(3):313-319.

We customize therapy based on each woman's unique needs. Your questions are welcome.

Madison Medical Compounding Pharmacy | 111 Fountains Blvd, Bldg B, Suite 2, Madison, MS 39110