## Record: 1

| Title:            | Menopausal hormone replacement therapy with continuous daily oral micronized estradiol and progesterone.   |
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| MeSH Terms:       | Menopause*<br>Estradiol/*therapeutic use<br>Progesterone/*therapeutic use<br>Cholesterol/blood ; Climacteric/drug effects ; Delayed-Action<br>Preparations ; Drug Administration Schedule ; Drug Combinations<br>; Estrogens, Conjugated (USP)/therapeutic use ; Female ; Humans<br>; Medroxyprogesterone/analogs & derivatives<br>; Medroxyprogesterone/therapeutic use ; Medroxyprogesterone Acetate<br>; Middle Aged ; Pilot Projects   |
| Abstract:         | The safety and efficacy of a daily combination of micronized estradiol (E2) (0.7-1.05 mg) and progesterone (200-300 mg) were evaluated in ten menopausal women with moderate to severe vasomotor symptoms and/or vaginal atrophy over a 12-month study interval. For comparison, five similar women were placed on conjugated estrogens, 0.625 mg daily, and medroxyprogesterone acetate, 10 mg daily, for the first 10 days of each calendar month for 12 months. Patients were evaluated at 0, 1, 3, 6, and 12 months. Estrogens rose significantly from baseline in both groups (P less than .01). Progesterone increased significantly above baseline in the E2 and progesterone group (P less than .01), but did not change in the conjugated estrogens and medroxyprogesterone acetate users. All women on E2 and progesterone had a decrease in total cholesterol and an increase in high-density lipoprotein cholesterol from baseline (P less than .01). Those on conjugated estrogens and medroxyprogesterone acetate had no significant change from baseline in total cholesterol; however, they did have an increase in high-density lipoprotein cholesterol values (P less than .01). In the E2 and |

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progesterone group, the endometrial histology became completely quiescent and there was no uterine bleeding after 6 months of observation. Four of five women on conjugated estrogens and medroxyprogesterone acetate continued regular withdrawal bleeding throughout the study period, but no endometrial hyperplasia was encountered. This study demonstrates that the daily administration of a combination of micronized E2 and progesterone results in symptomatic improvement, minimal side effects, an improved lipid profile, and amenorrhea without endometrial proliferation or hyperplasia in menopausal women.

 Substance Nomenclature:
 0 (Delayed-Action Preparations)

 0 (Drug Combinations)
 0 (Estrogens, Conjugated (USP))

 4G7DS2Q64Y (Progesterone)

 4TI98Z838E (Estradiol)

 97C5T2UQ7J (Cholesterol)

 C2QI4IOI2G (Medroxyprogesterone Acetate)

 HSU1C9YRES (Medroxyprogesterone)

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