Micronized Progesterone Subdues Hot Flashes

VITALS

Major Finding: Postmenopausal women who took oral micronized progesterone for 12 weeks had a 56% decrease in vasomotor symptoms from baseline, compared with 28% who took placebo.

Data Source: Randomized, placebo-controlled study of 133 postmenopausal women seeking hormonal therapy for hot flashes and night sweats.

Disclosures: The trial was funded by the Centre for Menstrual Cycle and Ovulation Research. Besins Healthcare and Schering Canada donated the progesterone and placebo used in the study.

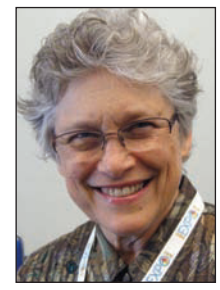
BY DOUG BRUNK

FROM THE ANNUAL MEETING OF THE ENDOCRINE SOCIETY

SAN DIEGO — Postmenopausal women who took oral micronized progesterone for 12 weeks had significant improvements in vasomotor symptom scores as well as significant reductions in the number of daily vasomotor symptoms, results from a randomized, placebo-controlled trial showed.

"If we know that progestin works, why would we investigate oral micronized progesterone?" mused Dr. Jerilynn C. Prior of the Centre for Menstrual Cycle and Ovulation Research at the University of British Columbia, Vancouver, at the meeting. Firstly, "it's molecularly identical to what our own bodies make, so we can make clear inferences about the metabolism of this hormone in our bodies." Also, it's approved by the Food and Drug Administration, and it has been shown in randomized controlled trials to improve sleep and cause no problems with cognition.

During June 2003 through October 2009, she and Christine Hitchcock, Ph.D., recruited 133 healthy postmenopausal women seeking hormone therapy for hot flashes and night sweats and randomized them to receive three 100-mg capsules of oral micronized progesterone (Prometrium) or placebo at bedtime nightly for 12 weeks. The time since their last menstrual flow was 1-10 years.



Micronized progesterone is 'molecularly identical to what our own bodies make.'

DR. PRIOR

Study participants were asked to record the intensity and number of vasomotor symptoms in a daily diary, and the researchers calculated their average daily vasomotor symptom score during the last 28 days of therapy, as well as the average number of vasomotor symptoms they experienced per day.

Women who had been on any kind of hormonal therapy within the previous 6 months were excluded from the trial, as were those with cardiovascular disease at baseline, and those who had difficulty completing the Daily Menopause Diary.

At baseline, the mean age of the 127 women with complete data was 55, their mean body mass index was 25 kg/m^2, and 91% were white. Their average vasomotor symptom score was 17, and they had an average of 6.8 vasomotor symptoms per day.

At the end of 12 weeks, women in the oral micronized progesterone group had a 56% improvement in vasomotor symptom scores and a 48% reduction in the number of vasomotor symptoms per day, while those in the placebo group had a 28% improvement in vasomotor symptom scores and a 22% reduction in the number of vasomotor symptoms per day.

"Oral micronized progesterone is highly effective therapy for hot flashes and night sweats," Dr. Prior concluded. "We saw no serious side effects in this trial, and there were numerically more dropouts in the placebo arm than in the treatment arm." The investigators are evaluating several other measures collected during the trial, "including what happens when women stop oral micronized progesterone, since we know that some women experience a rebound greater increase when they stop estrogen." ■