Clinical Trial Summary

The Effect of Herbal Extract (Profemin) on Pre, Peri and Post-Menopausal Women: A Randomized Double-blind, Placebo -controlled Study

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This clinical research study was designed to evaluate the efficacy of a new herbal product, Profemin, containing a mixture of standardized extracts of Cynanchum wilfordii, Phlomis umbrosa and Angelica gigas, on menopausal symptoms. This randomized double-blind, placebo-controlled trial was performed for 12 weeks with 64 pre-, peri- and postmenopausal White Hispanic, White non-Hispanic and African American women who were randomly allocated to either the Profemin group (n = 31) or the placebo group (n = 33). Primary end-points were the mean change in scores of the Kupperman menopause index (KMI) that evaluates 11 symptoms, and the mean change in scores of vaginal dryness. The mean KMI score was significantly reduced in the Profemin group from 29.5_7.4 at baseline to 11.3_5.8 ($p<0.01$) compared with change of the placebo group (29.2_6.6 at baseline vs 23.7_7.7 at week 12). The constituting symptoms of vasomotor, paresthesia, insomnia, nervousness, melancholia, vertigo, fatigue and rheumatic pain were significantly improved in the Profemin group in comparison with the placebo group ($p<0.05$). Statistically significant improvement in vaginal dryness in the Profemin group was also observed compared with that of the placebo group ($p<0.05$). In conclusion, Profemin significantly improved the menopausal symptoms of pre-, peri- and post-menopausal women without weight gain or any serious side effects.