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Femenessence Macapause Abstract

Hormone-balancing and Pharmacological Effects of Therapeutic Doses of *Lepidium peruvianum* (Maca-GO) in postmenopausal women

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Objective: To examine hormone-balancing effects of therapeutic doses of gelatinized organic preparation of *Lepidium peruvianum* Chacon (Maca-GO) in model pharmacological laboratory Trials and on early postmenopausal women in a multi-centre clinical study.

Design: Participants for this 3-month (one month placebo and 2 month treatment), double-blind, randomized, placebo-corrected, study were women who were in good health, ceased menstruation (>6 and <18 months), and were not using hormone replacement therapy prior to the study. Adopting a criterion of E2 <40pg/ml and FSH >30 IU/ml levels in a blood at the baseline, total 100 women volunteers were enrolled. They self-administered two hard gel capsules twice daily, each containing 500mg Maca-GO or identical-appearing placebo capsules containing inert ingredients. At baseline and follow-up monthly intervals, the following measurements were recorded by gynecologists in four clinics: level of sex hormones: E2, FSH, LH and Progesterone (PG), index of menopausal symptoms according to Kupperman (KMI). Additionally, in a 28-day parallel study on ovariectomised (by laparotomy) Wistar rats, the effect of 2 x 250mg/kg body weight (b.w.) Maca-GO daily on antidepressive function (Porsolt's test), anxiolytic sedative and cognitive effects (using elevated-plus maze, locomotor activity and passive avoidance tests) were assessed against control (laparotomised rats only). Prior to the study, toxicity of used Maca-GO was determined analytically and in bioassay on mice and rats.

Results: Analytically-determined non-toxic status of Maca-GO was confirmed in bioassays when applied to mice and rats at levels of 7.5 and up to 15g/kg b.w. Two months administration of Maca-GO significantly increased ($P<0.05$) E2 and reduced ($P<0.05$) FSH levels in 89 women who concluded the study and alleviated ($P<0.05$) symptoms of menopausal discomfort as assessed by the KMI (from 43 to 17). Maca-GO showed a distinctive, ($P<0.05$) antidepressant-like and sedative effect in ovariectomised rats only, while there was no anxiolytic activity nor disturbance of cognitive function observed in both, test and control animals.

Conclusion: Observed in this study balancing effect of Maca-GO on sex hormone levels and reduction in KMI score, show its value as a non-hormonal plant alternative to HRT program, relieving most of the symptoms experienced by women not only in early post-menopause, but potentially even more so at the pre-menopausal stage.