



Hormone-balancing Effect of Pre-Gelatinized Organic Maca (*Lepidium peruvianum* Chacon):

(II) Physiological and symptomatic responses of early-postmenopausal women to standardized doses of Maca in Double Blind, Randomized, Placebo-Controlled, Multi-Centre Clinical Study

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ABSTRACT

Objective: This was a double-blind, randomized, placebo-corrected, outpatient, multi-centre (five sites) clinical study, in which a total of 168 Caucasian early-postmenopausal women volunteers (age >49 years) participated after fulfilling the criteria: follicle stimulating hormone (FSH) >30 IU/ml and estrogen (E2) <40pg/ml levels at admission.

Design: Women were randomly allocated to Placebo and Pre-Gelatinized Organic Maca (Maca-GO) treatment, according to different monthly treatment sequences scheduled for each site. Two 500mg vegetable hard gel capsules with Maca-GO or Placebo powder were self-administered twice daily with meals (total 2g/day) during three (Trial I; n=102) or four (Trial II; n=66) months study periods..

Methods: At the baseline and follow-up monthly intervals, blood levels of FSH, E2, progesterone (PRG) and luteinizing hormone (LH), as well as serum cholesterol (CHOL), triglycerides (TRG), high- and low density lipoproteins (HDL and LDL) were measured. Menopausal symptoms were assessed according to Greene's Score (GMS) and Kupperman's Index (KMI). Data were analyzed using multivariate technique on blocs of monthly results in one model and Maca versus Placebo contrast in another model.

Results: A total of 124 women concluded the study. Maca-GO significantly stimulated production of E2 ($P < 0.001$) with a simultaneous suppression ($P < 0.05$) of blood FSH, increase ($P < 0.05$) in HDL. Maca-GO significantly reduced both frequency and severity of individual menopausal symptoms (hot flushes and night sweating in particular) resulting in significant ($P < 0.001$) alleviation of KMI (from 22 to 10).

Conclusion: Maca-GO offers an attractive non-hormonal addition to the choices available to early-postmenopausal women in the form of a natural plant alternative to Hormone Replacement Therapy (HRT) – hence, reducing dependence on hormone therapy programs

Short title: Maca in Postmenopausal Women: (II) Multi-Centre Clinical Study

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