

## EFFECTS OF THE PHYTOESTROGEN GENISTEIN ON SOME PREDICTORS OF CARDIOVASCULAR RISK IN OSTEOPENIC, POSTMENOPAUSAL WOMEN: A RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED STUDY

<u>Marini Herbert</u><sup>1</sup>, Minutoli Letteria<sup>2</sup>, Polito Francesca<sup>2</sup>, Bitto Alessandra<sup>2</sup>, Altavilla Domenica<sup>2</sup>, Frisina Nicola<sup>3</sup>, D'Anna Rosario<sup>4</sup>, Lubrano Carla<sup>5</sup>, Adamo Elena B<sup>1</sup>, Caputi Achille P.<sup>2</sup> and Squadrito Francesco<sup>2</sup>

<sup>1</sup>Dept. of Bioch., Phys. and Nutr. Sci., <sup>2</sup>Dept. of Clin. and Exp. Med. and Pharm., <sup>3</sup>Dept. of Int. Med., <sup>4</sup>Dept. of Obst. and Gyn. Sci., Messina; <sup>5</sup> Dept. of Med. Physiop., "La Sapienza" Univ., Rome, Italy

Genistein, a soy isoflavone, has received a great deal of attention over the last years because of its potential preventive role against cardiovascular diseases. We studied the effects of genistein administration (54 mg/day) on some predictors of cardiovascular risk in osteopenic, postmenopausal women in a randomized, double-blind, placebo-controlled trial. 389 osteopenic, postmenopausal women who were 49-67 years of age, were enrolled in 3 Italian university medical centers. After a 4-week stabilization on a standard fat-reduced diet, participants were randomly assigned to receive genistein (n=198) or placebo (n=191), daily for 24 months. Both intervention and placebo contained calcium and vitamin D. We measured blood lipid profile, fasting glucose, fasting insulin, HOMA-IR, fibrinogen, sICAM, sVCAM, F2-isoprostanes and osteoprotegerin (OPG) at baseline, after 12 and 24 months of treatment. By comparison with placebo, genistein significantly reduced fasting glucose, fasting insulin

By comparison with placebo, genistein significantly reduced fasting glucose, fasting insulin and HOMA-IR after 12 and 24 months of treatment. By contrary, the isoflavone administration did not affect blood lipids. After 24 months genistein-treatment, fibrinogen, F2- isoprostanes, sICAM and sVCAM decreased significantly compared to placebo while in the genistein group serum OPG was higher than in placebo. At the end of 24 months, genistein did not change endometrial thickness compared to placebo and most treatment-related adverse events were a moderate number of gastrointestinal side effects.

This study suggests that genistein has a favourable effect on some predictors of cardiovascular risk in a moderately size of osteopenic, postmenopausal women.