

Soy tablets not associated with reduction in bone loss or menopausal symptoms

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Soy isoflavone tablets do not appear to be associated with a reduction in bone loss or menopausal symptoms in women within the first five years of menopause, according to a report in the August 8 issue of *Archives of Internal Medicine*, one of the JAMA/Archives journals.

The beginning stages of menopause are often accompanied by rapid bone loss, hot flashes, vaginal dryness and sleep disturbances among other symptoms, according to background information in the article. "Estrogen therapy with or without progesterone prevents most of these changes. However, as a result of the Women's Health Initiative findings suggesting that the overall risks outweigh the benefits, most menopausal women now decline estrogen therapy, increasingly seeking other alternatives," the authors write. "Soy-derived products have been proposed to provide comparable benefits to estrogens but without the risks."

Silvina Levis, M.D., of the Miami Veterans Affairs Healthcare System and Miller School of Medicine, University of Miami, and colleagues, conducted a <u>randomized controlled trial</u> from July 2004 to March 2009 to determine the effectiveness of soy isoflavone tablets in preventing bone loss and other menopausal symptoms. <u>Study participants</u> received a soy isoflavone dose equivalent to approximately two times the highest intake through food sources in a typical Asian diet to ensure they received an effective dose. Women 45 to 60 years of age, within five years of menopause and with a <u>bone mineral density</u> T score (<u>bone density</u> compared with what is normally expected in a healthy young



adult of the same sex) of -2.0 or higher in the lumbar spine or total hip were eligible for the study.

A total of 248 women were eligible for the study; 126 were randomized to the group receiving placebo tablets and 122 were randomized to the soy isoflavone group, who received 200 mg of soy isoflavone tablets daily. During two years of follow-up, no significant differences were found between women in the soy isoflavone group and placebo group regarding changes in bone mineral density of the spine (-2 percent vs. -2.3 percent), the total hip (-1.2 percent vs. -1.4 percent) or the femoral neck (-2.2 percent vs. -2.1 percent), respectively.

Additionally, the number of menopausal symptoms was comparable between the two groups at baseline and the end of the study, except hot flashes. At the end of the study, 48.4 percent of women in the soy isoflavone group and 31.7 percent of women in the placebo group reported hot flashes. The authors also found that a higher number of women in the soy group reported constipation compared with women taking placebo (31.2 percent vs. 20.6 percent) but this was not statistically significant.

"Because of concerns regarding the risk of estrogens, a need exists for alternative interventions that could provide the beneficial effects of estrogens in bone and menopausal symptoms without the adverse effects on breast and cardiovascular health," the authors conclude. However, "we found that our population of women in the first five years of menopause, on average, had low rates of bone loss, and that 200 mg of soy isoflavone tablets taken once daily does not prevent bone loss or reduce bone turnover or menopausal symptoms."

More information: Arch Intern Med. 2011;171[15]:1363-1369



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