Prostate cancer chemoprevention study: an investigational randomized control study using purified isoflavones in men with rising prostate-specific antigen.


Abstract

Our previous case-control study suggested that equol, a metabolite of isoflavone, has a preventive effect on prostate cancer. To examine the prostate cancer risk based on isoflavone intake and equol production, we carried out a phase II, randomized, double-blind, placebo-controlled trial of oral isoflavone (60 mg/day) for 12 months. The inclusion criteria were Japanese men between 50 and 75 years of age, a serum prostate-specific antigen level of 2.5-10.0 ng/mL, and a single, negative prostate biopsy within 12 months prior to enrollment. The study included 158 men in eight Japanese centers. Their median age was 66.0 years, and the numbers of equol producers and non-producers were 76 (48%) and 82 (52%), respectively. The majority of adverse events were mild or moderate in severity, and the scheduled intake of tablets was completed by 153 patients (96.8%). The prostate-specific antigen value showed no significant difference before and after treatment. Of the 89 patients evaluated by central pathological review, the incidence of biopsy-detectable prostate cancer in the isoflavone and placebo groups showed no significant difference (21.4% vs 34.0%, P = 0.140). However, for the 53 patients aged 65 years or more, the incidence of cancer in the isoflavone group was significantly lower than that in the placebo group (28.0% vs 57.1%, P = 0.031). These results support the value of isoflavone for prostate cancer risk reduction. A large-scale phase III randomized study of isoflavone tablets in men with different hereditary factors and living environments is warranted. Registered with the UMIN Clinical Trials Registry (UMIN-CTR) for clinical trials in Japan (C000000446).


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