

Clinical Characteristics and Pharmacokinetics of Purified Soy Isoflavones: Single-dose Administration to Healthy Men

Busby, M.G., **Jeffcoat, A.R.**, Bloedon, L.T., **Koch, M.A.**, Black, T., **Dix, K.J.**, Heizer, W.D., **Thomas, B.F.**, **Hill, J.M.**, et al. (2002). Clinical characteristics and pharmacokinetics of purified soy isoflavones: single-dose administration to healthy men. *American Journal of Clinical Nutrition*, 75 (1):126-136.

Soy products containing isoflavones are claimed to decrease cholesterol, ameliorate the effects of menopause, and lower the risk of certain cancers, including prostate, breast, and colon cancer. Some particular soy isoflavones, such as genistein and daidzein, have also been reported to inhibit the growth of different types of cancer cells in culture. However, the mechanism of action behind the variety of putative therapeutic activities is often unclear or complicated. As with many food products or “nutraceuticals,” the concentration of isoflavones ingested and absorbed may vary dramatically due to preparation, storage, or other factors. Thus, it seems reasonable to advise caution when consuming soy products for particular therapeutic benefits until a clearer understanding is gained of the dose-response relationships involved. To provide additional information regarding what happens to isoflavones in humans, we conducted safety studies of purified unconjugated genistein, daidzein, and glycitein in higher doses than those previously administered to humans and defined pharmacokinetic parameters for their absorption and metabolism.



Robert Jeffcoat



Matthew Koch



Brian Thomas

Thirty men (aged 40-69 yrs), whose good health was verified by a medical history and physical examination conducted by a licensed medical doctor, screening laboratory tests, chest X-ray, and electrocardiogram, completed the study. Laboratory assays were repeated on days 1 (predose and 24 h postdose), 3, 6, 14, and 30; subjects also received a chest X-ray and an electrocardiogram again on day 30. After a single oral administration, the plasma half-life of the isoflavones was relatively short, regardless of whether in a free (<4 h) or conjugated form (<10 h). Even though some of the single doses administered in this study exceeded normal dietary intake manifold, we observed no significant clinical chemistry or physical changes after treatment.

Link: <http://www.ajcn.org/cgi/content/abstract/75/1/126>