

A Meta-Analysis of 46 Studies Identified by the FDA Demonstrates that Soy Protein Decreases Circulating LDL and Total Cholesterol Concentrations in Adults.

BACKGROUND:

Certain plant foods (nuts and soy protein) and food components (viscous fibers and plant sterols) have been permitted by the FDA to carry a heart health claim based on their cholesterol-lowering ability. The FDA is currently considering revoking the heart health claim for soy protein due to a perceived lack of consistent LDL cholesterol reduction in randomized controlled trials.

OBJECTIVE:

We performed a meta-analysis of the 46 controlled trials on which the FDA will base its decision to revoke the heart health claim for soy protein.

METHODS:

We included the 46 trials on adult men and women, with baseline circulating LDL cholesterol concentrations ranging from 110 to 201 mg/dL, as identified by the FDA, that studied the effects of soy protein on LDL cholesterol and total cholesterol (TC) compared with non-soy protein. Two independent reviewers extracted relevant data. Data were pooled by the generic inverse variance method with a random effects model and expressed as mean differences with 95% CI. Heterogeneity was assessed and quantified.

RESULTS:

Of the 46 trials identified by the FDA, 43 provided data for meta-analyses. Of these, 41 provided data for LDL cholesterol, and all 43 provided data for TC. Soy protein at a median dose of 25 g/d during a median follow-up of 6 wk decreased LDL cholesterol by 4.76 mg/dL (95% CI: -6.71, -2.80 mg/dL, $P < 0.0001$; $I^2 = 55%$, $P < 0.0001$) and decreased TC by 6.41 mg/dL (95% CI: -9.30, -3.52 mg/dL, $P < 0.0001$; $I^2 = 74%$, $P < 0.0001$) compared with non-soy protein controls. There was no dose-response effect or evidence of publication bias for either outcome. Inspection of the individual trial estimates indicated most trials (~75%) showed a reduction in LDL cholesterol (range: -0.77 to -58.60 mg/dL), although only a minority of these were individually statistically significant.

CONCLUSIONS:

Soy protein significantly reduced LDL cholesterol by approximately 3-4% in adults. Our data support the advice given to the general public internationally to increase plant protein intake.