

High doses of saw palmetto appear safe over 18 months

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Noting that saw palmetto berry extracts are used as self-treatment for lower urinary tract symptoms associated with [benign prostatic hyperplasia](#), Andrew L. Avins, M.D., M.P.H., from Northern California Kaiser-Permanente Division of Research in Oakland, and colleagues examined the safety of saw palmetto extract among 357 men participating in the [Complementary and Alternative Medicine for Urological Symptoms](#) trial. During 18 months of follow-up, participants were randomized to receive 320, 640, and 960 mg daily of an ethanolic

saw palmetto extract in an escalating manner at six-month intervals or to an identical-appearing placebo.

The researchers found that there were no significant between-group differences in the rates of serious or non-[serious adverse events](#), changes in vital signs, findings on digital prostate examination, or rates of study withdrawal. There were also no significant differences in laboratory test abnormalities between the groups. Differences in individual laboratory tests were small in magnitude and occurred rarely. There was no evidence of a dose-response effect of saw palmetto.

"Our data suggest that saw palmetto is unlikely to be associated with important, common toxicity for up to 18 months," write the authors. "While the most recent clinical evidence does not support the superiority of saw palmetto over placebo, it appears that men who elect to try the supplement are unlikely to have substantial adverse medical consequences from short-term use."

Placebo and saw palmetto extract were provided by Rottapharm/Madaus. One author disclosed [financial ties](#) to the Informed Medical Decisions Foundation.

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