

A phase II study of pomegranate extract for men with rising prostate-specific antigen following primary therapy.

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Abstract:

Background: Pomegranate extract (POMx) demonstrates promising antitumor effects in prostate cancer (PCA). Prior published work reveals an increase in PSA doubling time (PSADT) in a single arm study of pomegranate juice (POM) in PCA patients (pts) with a rising PSA after local therapy. We sought to determine the effects of low (1 gram) or high (3 grams) daily POMx on PSADT in a similar but broader population of men seeking to defer androgen deprivation therapy. **Methods:** Our multi-center, double blind phase II trial randomized men with rising PSA and without metastases to receive high or low dose POMx, stratified by baseline PSADT and Gleason score, and with no restrictions for PSADT and no upper limit PSA value. Men were treated until progression or for 18 months. PSA levels were obtained every 3 months. This study was designed to detect a 6 month increase in PSADT from baseline. **Results:** 104 patients were enrolled and treated for up to 6 (92%), 12 (70%) and 18 months (36%). Median PSADT lengthened in the Intent to treat population (96% white, median age 74.5 years, median Gleason score 7) from baseline 11.9 (range 1.6-54.6) compared to 18.5 (2-1523) months after treatment ($p < .001$). There was no significant treatment difference on PSADT between the dose groups ($p = .920$). Declining PSA levels were observed in 13 pts (13%) during the study. No significant changes occurred in testosterone in either group. Although no clinically significant toxicities were seen, mild to moderate diarrhea was seen in 8 pts (7.7%). **Conclusions:** POMx treatment significantly increased the PSADT by over 6 months in both treatment arms, with no effect on testosterone. This IND-conducted study confirms slowing of PSADT after treatment with POMx as was found with POM, yet in a PCA patient population with greater high risk progression features.