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Safety and Tolerability of Panax ginseng Root Extract: A Randomized, Placebo-Controlled, Clinical Trial in Healthy Korean Volunteers.

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Abstract

Abstract Objectives: **Panax ginseng** has been extensively used as an adaptogen and is among the top 10 selling herbal supplements in the United States over the past decade. However, there have been few reports about the toxicity of **P. ginseng** in human studies. Given the lack of toxicological studies in human, this study investigated whether **P. ginseng** administration causes any noticeable toxic effects in healthy volunteers. **Methods:** This study was designed as a randomized, double-blind, placebo-controlled, and parallel group trial in healthy volunteers. The subjects were required to be healthy, free from any significant disease, as assessed at screening by physical examination, medical history, and laboratory (hematological and biochemical) tests. Eligible subjects received **P. ginseng** extract (1 g/day or 2 g/day) or placebo over a 4-week period. **Results:** Although mild adverse events, such as dyspepsia, hot flash, insomnia, and constipation, were reported in both **P. ginseng** and placebo group, no serious untoward reactions were reported following **P. ginseng** administration. Nonsignificant changes were observed in hematological and biochemical tests. **Conclusions:** **P. ginseng** administration for 4 weeks was shown to be safe, tolerable, and free of any untoward toxic effect in healthy male and female volunteers. Future results from ongoing multicenter collaborative efforts to evaluate short- and long-term effects of **P. ginseng** may contribute to our current understanding of safety and tolerability of this herbal product.

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