

 **International Journal of Medicinal Mushrooms**

ISSN for PRINT: 1521-9437

Institutional price: \$581.00

Issues per year: 4

For Online Access

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 **2005, Volume7**Issue 1&2 **344**  
pages

DOI: 10.1615/IntJMedMushr.v7.i12

**● Clinical Trials for Medicinal Mushrooms: Experience with *Ganoderma lucidum* (W.Curt.:Fr.) Lloyd (Lingzhi Mushroom)****Shufeng Zhou**

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**ABSTRACT**

Despite the popularity of medicinal mushrooms, most are not well researched in terms of clinical efficacy and toxicity. We have completed seven clinical trials of *Ganoderma lucidum* in several diseases including cancer, Type II diabetes, coronary heart disease, chronic hepatitis B, and neurasthenia. Most of these studies were randomized, double-blind, multi-centered and placebo controlled. The results arising from these studies are promising. For example, treatment with Ganopoly for 12 weeks showed hypoglycemic activity in Type II diabetes, improved the symptoms/signs of patients with coronary heart disease or neurasthenia, and produced some antiviral and liver protective effects in patients with chronic hepatitis B infection. However, the same treatment regimen did not result in any objective response in late-stage cancer patients, although some stable disease status was observed. Ganopoly appeared to enhance immune functions in some cancer patients, but the results have yet to be confirmed. Ganopoly was generally well tolerated. Overall, the findings from all these clinical studies suggest that Ganopoly may have multiple pharmacological activities, although the activities are minor, moderate, or lacking as a result of many factors, such as inappropriate dosage regimen, difficulties in finding suitable biomarkers and end points, large interpatient variability in responses to the treatment, and unknown mode of action. Well designed clinical studies are needed to explore the mode of action, efficacy and safety of *G. lucidum* in patients.

DOI: 10.1615/IntJMedMushr.v7.i12.110

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