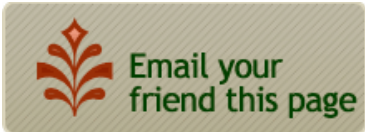


PSP CAPSULES IN CLINICAL CARE THERAPY  
 (A BRIEF SUMMARY OF CLINICAL TRIALS PHASE I, II AND III TRIALS)



[Clinical Trials \(China\)](#)
[Clinical Trials \(Hong Kong\)](#)
[What are Clinical Trials](#)

Polysaccharide-peptide (PSP) is a protein bound polysaccharide isolated from the COV-1 strain of Yunzhi (Coriolous versicolor mushroom) and made from modern alcohol extraction techniques. Each capsule contains 0.34 grams of PSP. Experimental in-vitro and in-vivo studies have shown PSP inhibits the proliferation of cancer cells including P338 leukemia cells, S 180 cells, Ehrlich ascites, and stomach and lung cancer cells. It also inhibits the growth of some tumors such as the lymphatic tumor of human skin tissue cells. In addition, PSP affects the immune system of mice by stimulating the production of  $\alpha$  interferons, increasing the phagocytic index and metabolic rate of the reticuloendothelial system and by raising the HC 50 (median hemolytic dose), IgG and PFC (plaque forming cell) values. Human in-vivo experiments have also shown PSP can modulate the immune system by helping to prevent and partly eliminate the side effects of radiation and chemotherapeutic agents used by cancer patients.

<b>Phase I Clinical Trial</b>	<b>Phase II Clinical Trial</b>	<b>Phase III Clinical Trial</b>
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In 1991, a clinical phase I study was carried out by Dr. Guo-ming Xu of Changhai Hospital in Shanghai to assess the feasibility of using this agent clinically by observing healthy human subjects taking PSP for any possible toxic side effects and adverse reactions. Twenty-one people, including 16 healthy volunteers and 5 post-operative breast cancer patients without recurrence or metastases were equally divided into three groups to take a total of two, four or six grams of PSP each day respectively. Each dosage was divided equally into capsules that were taken after each meal three times a day for 30 days. Symptoms of abdominal pain, diarrhea,

constipation, poor appetite, headache, dizziness, skin rash, itching, palpitation, stuffy chest, and urinary frequency were monitored. An electrocardiogram (ECG) and laboratory parameters including peripheral blood counts (hemoglobin, white blood cells, red blood cells and platelets), liver function and renal function tests were compared before and after PSP was taken for the study duration.

Results of the phase I trial found no significant toxic side effects or adverse reactions related to PSP intake. No abnormal changes in the ECG and laboratory tests mentioned above were observed in any group taking PSP. Four people experienced a slight degree of loose bowels, which occurred less than twice a day (2 people taking 2gms of PSP/day, 1 person taking 4gms of PSP/day and 1 person taking 6gms/PSP day). Positive effects of taking PSP were also noted. Eleven people (52.8%) developed an increase of appetite, which was most noticeable in the group taking six grams of PSP/day (n=6). Based on the results of this study, PSP was considered safe to use clinically and a Phase II clinical trial was undertaken in cancer patients.

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#### Conclusion

Besides the patients studied in the prospective clinical trials, individuals with other malignancies such as nasopharyngeal carcinoma, melanoma, colon rectal cancer, cervical cancer, lymphoma, hepatoma, breast cancer and others have used PSP capsules during or after surgery, chemotherapy and radiation therapy in China and Hong Kong for several years. Most of these individuals report feeling improvement in their general condition, appetite, energy level, and ability to digest food. As a biological response modifier, PSP may help them to improve or maintain their immune status while decreasing the severity of the side effects associated with chemotherapy and radiation. Its safety profile also makes it an ideal adjunct therapy to help in the treatment of cancer. Further research is necessary to verify these findings in other malignancies.

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