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

Clinical Trials (China) TOP ıical 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 α\interferons, increasing the phagocytic index and metabolic rate of the reticuloendothilial 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.

Phase I Clinical Trial | **Phase II Clinical Trial** | **Phase III Clinical Trial**

Based on the PSP´s significant findings in the investigated cancers of the Phase II trial, permission was granted by the Chinese Administration of Health Bureau to carry out a multi-center Phase III clinical trial. Fourteen hospitals including the eight who participated in the phase II trial conducted this randomized study from April 1996 to September 1997.

Six hundred and fifty patients with either stomach, lung or esophageal cancer entered the study. Standard cancer treatment mainly consisted of surgery, chemotherapy and/or radiation therapy. Chemotherapy and

radiation treatment lasted for approximately two months and followed the same regimens as the phase II trial. See Table 2. Patients were randomly divided into a treatment (n=96) and control group (n=93). The open group consisted of 461 patients where both the physicians and patients knew they were taking PSP. See Table 4 for a breakdown of each type of cancer. Patients in the treatment and open group received one gram of PSP three times a day for two months. The control group received 150mg Batilol three times a day for two months. Both therapies were given concurrently with the start of chemotherapy or radiation therapy. Evaluation of effectiveness of treatment was the same as the phase II trial.

Table 4

Type of cancer	No. Control Group	No. Treatment Group	No. Open Group
Stomach	30	30	170
Lung	33	35	129
Esophagus	30	31	162
Total	93	96	461

The Phase III trial showed similar results to the Phase II trial. The overall response rate (combination of patients which had treatment that was "effective" or "markedly effective") for the treatment group (87.5%) was significantly higher than the control group (41.9%) ($p<0.01$). The open group also had an 85.5% overall response rate. Like the phase II, the overall response of treatment group patients with stomach, lung and esophagus cancer was also significantly higher when compared with the same cancers of the control group ($p<0.01$). See Table 5 for overall effectiveness of PSP in the different types of cancer.

Stomach Cancer

	Table 5	Lung Cancer	Esophagus Cancer
Control Group	42.4%	42.4%	43.3%
Treatment Group	90%	85.7%	87%
Open Group	85.3%	86.0%	85.2%

The treatment group experienced a highly significant decrease ($p<0.01$) in symptoms of fatigue, loss of appetite, and mouth or throat dryness and a significant decrease in anorexia and vomiting, sweating, and pain ($p<0.05$) compared to the control group. The Karnofsky performance status is used as an evaluation of quality of life. The majority of patients taking PSP, n=79 in the treatment group, n=257 in the open group and n=65 in the control group had a stable Karnofsky score (score change of less than 10) after treatment. However, the control group had a 22.6%

Conclusion

decrease in Karnofsky scores after treatment compared with only 5.2% in the treatment group and 3.7% in the open group. This result suggests PSP helps cancer patients to maintain their quality of life and level of functioning after chemotherapy and radiation. A weight increase of one kilogram or more was seen in 40% of the treatment group and 47.2% in the open group as compared to only 15.1 % in the control group ($p<0.05$).

While there were decreases in the WBC and Hgb levels after chemotherapy and radiation in all the groups tested, the decreases were significantly less in the treatment group compared with the control group ($p<0.01$). No significant changes were seen in the RBC (red blood cell) levels. The CD4+/CD8+ ratios remained stable after taking PSP in both the treatment and open groups. However, the control group had a significantly lower CD4+/CD8+ ratio (1.16 0.59) compared to the treatment group (1.61 0.77) after taking PSP ($p<0.01$). Unlike the phase II trial, no significant changes in NK activity were seen in any of the tested patients before or after treatment. Both the treatment and open group experienced an increase in IL-2 production after treatment with PSP. The increase in the treatment group went from 32.84 16.39 to 37.59 19.73 ($p<0.05$), which was significantly higher then the control group (31.94 12.65) after taking Batilol ($p<0.01$). Among the 650 patients tested in the trial, there were no significant changes seen the heart, liver and renal function after treatment with either PSP or Batilol from their baseline functioning.

The results of this phase III clinical trial were mostly consistent with the phase II clinical trial results. PSP was shown to be helpful in easing the side effects associated with chemotherapy and radiation. Biologically, PSP exhibited a protective effect on maintaining the immunological functions of patients receiving immunosuppressive radiation and chemotherapy. Thus, PSP can be classified as a clinical biological response modifier. The phase III clinical also demonstrated PSP can be used safely among stomach, lung, and esophagus cancer patients with no adverse effects on heart, renal or liver functions.

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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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