PSP CAPSULES IN CLINICAL CA THERAPY (A BRIEF SUMMARY OF CLINICA ASE I, II AND III TRIALS)

TOP

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 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**

In November 1991, in accordance with the approval document No. (91) ZL-15 of the Ministry of Public Health, the Shanghai Public Health Bureau appointed the following 8 hospitals to carry out a multi-center phase II clinical trial using PSP. They were the Long-Hua Hospital, Shu-Guang Hospital of the University of Chinese Medicine, Cancer Hospital of Shanghai Medical University, Shanghai Chest Hospital, Ren-Jin Hospital of the Second Medical University of Shanghai, The Third Textile Hospital of Shanghai, the Chang-Hai Hospital and the Chang-Zheng Hospital of the Second Military Medical University. This prospective double-blind study

took place from February to July 1992. The purpose was to investigate the safety and efficacy of using PSP as an adjunct to chemo and radiation therapy. Stomach, primary lung and esophagus cancers are the most prevalent malignancies found in Shanghai. Patients with these types of cancer were selected for the study. Diagnoses were confirmed by surgery, clinical tests and cell pathology reports. Patients were also diagnosed by Chinese medicine practitioners and were classified according to deficiency of vital energy, deficiency of body fluid and deficiency of heart and spleen.

Four hundred and eighty five patients were admitted to the study. Of those, 274 patients were randomly assigned to a control group (n=135) and treatment group (n=139) according to the types of cancers they had. The remaining 211 cases were admitted into an open non-random group in which the physicians knew they were being given PSP. See Table 1 for a breakdown of the types of cancer of each group. All patients received two courses of chemotherapy or radiation depending on the type of cancer. Each course lasted approximately one month. See Table 2 for treatment regimens. Patients in the treatment group received three 0.340 gram capsules of PSP three times a day. Patients in the open group also received the same PSP dosing schedule as patients in the treatment group. The control group was given three 50mg capsules of Batilol in the same packaging as the PSP three times a day. Therapy was initiated in all groups when chemotherapy or radiation was started and lasted for approximately two months.

Table 1

Cancer Type	Pathology	Total No. of Patients	Treatment group	Control Group	PSP open group
Esophagus	Squamous cell carcinoma	172	56	56	60
Esophagus	Adenocarcinoma	149	36	34	79
Esophagus	Undifferentiated squamous cell	13	3	5	5
Lung	Squamous cell	73	20	23	30
Lung	Adenocarcinoma	78	20	21	37
Total		**485**	**135**	**139**	**211**

Table 2Table 2

Cancer Type	Drug	Dose	Route	Frequency/th>	#of cycles
Stomach Cancer(MF Plan)	Mitomycin C	6-8mg	IV	Day 1 of 1month cycle	2
Stomach Cancer (MF Plan)	5FU	500-750mg	Ivgtt	Days 1-5 of 1 month cycle	-
Lung Cancer (MAP Plan)	Mitomycin C	10mg	IV	Day 1 of 1month cycle	2
---	Adriamycin	40mg/m2	Ivgtt	Day 1 of 1 month cycle	-

---	Metaclopromide	20 mg	Ivgtt	Day 1 of 1 month cycle	-
---	DDP	60-90mg/m2	Ivgtt	Day 1 of 1 month cycle	-
---	Vincristine (used instead of Adriamycin if patient had heart disease)	1mg/m2	IV	Day 1 of 1 month cycle	-
Esophagus Cancer	Radiotherapy8 Mv X-ray or Co60 -ray	65-70 GY	-	6-7 weeks	-

Clinical symptoms of weakness, feeling tired, poor appetite, nausea and vomiting, mouth and throat dryness, anxiety, insomnia, insomnia, palpitations, pain, shortness of breath, spontaneous or night sweating, tongue appearance and pulse quality were evaluated monthly. Body weight and Karnofsky´s performance standard (a quality of life assessment tool) were evaluated before and after treatment. Hematological parameters such as WBC´s (white blood cells), Hgb (hemoglobin), platelets, liver and renal function tests and immuno assays such as NK (natural killer) cells, interleukin 2 (IL-2), T cells and their subgroups with the exception of the WBC´s were all measured before and after treatment as well as on a monthly basis. Clinical symptoms and laboratory results were validated by the Chairman of TCM Clinical Research under the China´s Department of Health for both the phase II and phase III clinical trials.

Treatment with PSP was considered "effective" if clinical symptoms were markedly improved and the blood and immunological indexes remained stable or improved by a third or more. It was also considered "effective" if clinical symptoms markedly improved and the Karnofsky score or body weight remained equal or was improved compared to the control group. Treatment that had a "marked effect" had to satisfy all of the above criteria. Study results were recorded and analyzed according to the Bonferrori x2(Gtest), qualitative x2, and Ridit or Mann Whitney Wilcoxon U tests. Statistical significance was set at $p<0.05$.

The overall response rate (combination of patients which had treatment that was "effective" or "markedly effective") was significantly higher in the treatment group (82.0%) and open group (83.9%) compared to the control group (45.2%), ($p< 0.001$). When each group was further analyzed by the types of cancer, the PSP treated and open group still responded better then the control group regardless of the type of cancer (p G0.01). See Table 3 for results.

Table 3

Overall Effectiveness of Treatment			
	Stomach Cancer	Lung Cancer	Esophagus Cancer
Control	32.14%	32.50%	76.92%
Treatment	80.36%	70.45%	97.44%
Open	78.33%	71.64%	97.62%

No statistically significant differences were found between the treatment, open and control groups in terms of changes in WBC´s, Hgb, and platelets. The majority of the three groups had a stable hematological profile at the end of treatment period showing PSP had no adverse effect on these parameters in patients undergoing chemotherapy and radiation treatment. An important finding was the effectiveness of PSP in improving the immunological profiles of the patients. The rate of increase in activity of natural killer cells (NK) in the treatment (63.97%) and open groups (68.93%) was significantly higher than the control group (4.11%) ($p<0.001$). The treatment group also had a significant increase in the amount of interleukin 2 (IL-2) produced after taking PSP ($p<0.001$), whereas the control group did not ($p>0.05$). In addition, there was a tendency for the CD+4/CD+8 ratio to improve or remain stable in more PSP treated patients then control patients. No obvious renal, hepatic or cardiac toxicities were seen during the study period. Overall, the Phase II clinical trial showed PSP is safe and can help lessen the degree of side effects that chemotherapy and radiation produces. It also improved or maintained the immunological profiles of stomach, esophagus and lung 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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