Clinical Trial

ImmuneFX brand Dietary Supplement as an Adjunct for Chemo and Radiation Therapy in Cancer Treatment

Clinical Trial of a Mixture of Six Medicinal Mushroom Extracts

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See footnotes for explanation of trial and description of Polyactin-A

Abstract

This paper reports the results of a clinical trial conducted between August 2000 and April 2001 at the People's Hospital of Lishui City, Zhejiang Province, Peoples Republic of China, showing the clinical manifestations of a mixture of six Medicinal Mushroom extracts as an adjunct therapy to improve the immune function of cancer patients undergoing other therapies.

Methods

The Zhejiang Qingyuan Fungi Medicinal & Health Products Co., Ltd produced the experimental mixture used in this clinical trial. This mixture was formulated and is marketed in the United States of America and Canada under the trade name **ImmuneFX** where it has shown good results in cancer treatment. This mixture includes Alpha and Beta-Glucans and other polysaccharides, extracted from the following well-known species of medicinal mushrooms:

- Agaricus blazei (polysaccharide >40%)
- Lentinus edodes (polysaccharide >25%)
- Grifola frondosa (polysaccharide >28%)
- Ganoderma lucidum (polysaccharide >20%)
- Coriolus versicolor (polysaccharide >30%)
- Cordyceps sinensis mycelium (polysaccharide >30%)

These six extracts were mixed together into tablet form and co-administered along with chemotherapy or radiation therapy to the patients undergoing treatment as a daily regimen. This trial was conducted among 56 cancer patients, 30 chosen to receive the Medicinal Mushroom extract mix and another 26 comparable patients as a control group, receiving the accepted pharmaceutical drug Polyactin-A ô as a control group. All patients were in the middle-late stages (Stage 3 and 4) of cancer. Polyactin-A is made by Taixing Medicine Company, Ltd. in Chengdu, PRC and the lot number used was 20000327. Results: There are significant differences between the experimental group and the control group. The experimental group of patients had improvements in the disease progression and Quality of Life measurements as compared to the control group of cancer patients.

Discussion

This formulation of mixed polysaccharides, made up from the six species of Medicinal Mushrooms named, has great potential as a new health product for the improvement of immunity and showing high effectiveness and non-toxicity for use in cancer patients undergoing conventional therapy. Further trials are recommended.

Key words

Medicinal Mushroom extract, Beta-Glucan, polysaccharide, cancer, Immune function.

Introduction

It has been found recently that the Beta-Glucans and other polysaccharides, which can be extracted from medicinal fungi, are bioactive in many ways. Qingyuan County lies in the southwest of Zhejiang province in the Peoples Republic of China, and is one of the major sources of these medicinal fungi. We researched the folk remedies known in this area, and arranged the use of Royal Sun Agaricus mushroom (***A. blazei***), Maitake (***G. frondosa***), Shiitake (***L. edodes***), Reishi (***G. lucidum***), Turkey Tails (***C. versicolor***), and Caterpillar fungus (***C. sinensis***) as the main materials from which to extract the polysaccharides, and produced the **Immune Fx** formulation in tablets according to the known roles of the polysaccharides, such as inhibiting the growth of tumors and improving immunity. This research group found apparent roles of the polysaccharides among the tumor patients during these trials conducted between August 2000 and April 2001. The patients were being treated concurrently with radiotherapy or chemotherapy. The polysaccharide materials were provided by Zhejiang Qingyuan Fungi Medicinal & Health Products Co., Ltd., and formulated in accordance with the proprietary ImmuneFX formula developed by Jason Watkin of BioMedica Labs, Inc of Duncan, British Columbia. The Government research permit issued for this research is number 99-118. The tablets used in this trial were total weight 500 mg, of which the total polysaccharide content was 475 mg.

Materials and Methods

Study subject selection criterion:

1. The patients all had apparent pathological diagnoses;
2. The patients have had no surgery before or have had surgery but had a relapse, or have new transference of tumor about focus. They had clinical focus of the observation marker of X-ray and CT in order to estimate the curative effect;
3. The patients have normal function of liver and kidneys before treatment, a Kafnofsky score >60, and could be expected to live more than 3 months;
4. According to the international standard of TNM by stages, the middle-late cases are chosen; American measure of stage 3 and stage 4.
5. White Blood cell count > 4.0 X 109/L. blood platelet count > 100 x 109/L.
6. The patients were being treated concurrently by radiotherapy or chemotherapy.

The patients were all middle-late stage patients with malignant tumors in all 56 cases. Among the 56 cases, 30 cases were in the experimental group, and 26 cases were in the comparison group. The cases of the two groups all came as referrals for this trial from co-operative hospitals. The patients had similar conditions, such as physical condition, total number of white blood cell count and granular leukocyte count, appetite condition and the clinical treatment plans of radiotherapy or chemotherapy were almost the same. The total number of white blood cell count in the two groups had no apparent difference through comparison by statistical treatment before trials. The details of the two groups can be seen from tables 1 and 2.

Table 1

The common comparison between the two groups

	n	Gastric Carcinoma	Liver Carcinoma	Lung Carcinoma	Large Intestine Carcinoma	Naso-Pharyingeal Carcinoma
Experimental Group	30	6	10	4	5	5
Comparison Group	26	6	9	4	6	1

Table 2

The comparison of total number of white blood cells between the two groups before trials

Total Number of White Blood Cells (x 109/L)				
	n	<3.5-4.0	4.0-5.0	>5.0
Experimental Group	30	3 (10%)	21 (70%)	6 (20%)
Comparison Group	26	2 (7%)	19 (73%)	5 (19%)

2) Experimental methods:

The two groups had basically the same radiotherapy and chemotherapy plans, procedures and similar anti-nausea drug therapy (Shudan). The patients in the experimental group begin to take the polysaccharide tablets for one week before radiotherapy and chemotherapy, 3 x day, 4 tablets each time (total 6 grams/day). The patients in the comparison group begin to take the tablets of Polyactin A for one week before radiotherapy and chemotherapy, 3 x day, 10 mg each time (total 30 mg/day). Both groups continued to take the tablets during the course of treatment and afterwards for a total of 2 months.

3) Observation markers:

1. 4 classes of vomiting: 0 x/day, 1-2 x/day, 3-4 x/day, 5 or more x/day;
2. Appetite, 3 conditions of appetite: almost none or less than half of common food quantity consumed, half of common food quantity consumed, common food quantity consumed.
3. Alteration of hemogram (blood) test, total CBC: 3-4 times every 3 days before and after radiotherapy and chemotherapy.
4. Observation of other poison reactions i.e. loss of hair, changes in organ function; such as stomach, intestines, heart, liver, kidney, etc.
5. Divide the conditions of markers1-4 for the assessment of quality of life: According to the KPS, adding 10 points after treatment is considered improvement, increasing or decreasing by 4 points is stable, reducing 10 points or more is a decline of condition.

Results

After radiotherapy or chemotherapy, the comparison group had little changes in reaction for the digestive tract and the improvements in the total number of white blood cells was much less than that of the experimental group. The appetite and quantity of food taken showed great differences between the two groups. These can be seen from Tables 3, 4, 5 and 6.

Table 3

The alteration in blood count of the two groups after chemotherapy

		Total number of White Blood Cells (x 109/L)			Number of Granular Leukocyte	
	n	<3.0	3.0-4.0	>4.0	<50%	>50%
Experimental Group	30	4 (13%)	5 (17%)	21 (70%)	11 (37%)	19 (63%)
Comparison Group	26	5 (19%)	7 (27%)	14 (54%)	16 (62%)	10 (38%)

P<0.1 From the comparison of the two groups as to the number of white blood cells.

Table 4

Comparison of vomiting after treatment

	n	0 x/day	1-2 x/day	3-4 x/day	5+ x/day
Experimental Group	30	24 (80%)	2 (7%)	2 (7%)	2 (7%)
Comparison Group	26	18 (69%)	3 (12%)	3 (12%)	2 (8%)

P<0.01

Table 5

Appetite comparison after treatment

	n	< half servings food	half servings food	full servings food
Experimental Group	30	4 (13%)	17 (57%)	9 (30%)
Comparison Group	26	6 (23%)	12 (46%)	8 (30%)

P<0.01

Table 6

Comparison of KPS value between the two groups

	n	Improvement or stable (%)	Decline (%)
Experimental Group	30	23 (78%)	2 (22%)
Comparison Group	26	19 (73%)	7 (27%)

The result indicates the score of the experimental group is higher than that of the comparison group.

Poison reactions

The reaction of the digestive tract is very light for the two groups, the experimental group is 30% (9/30), and the comparing group is 50% (13/26); The conditions of loss of hair is 8.3% in the experimental group and 10% in the comparison group. The patients of the two groups show no abnormalities of the heart, liver and kidneys. There were two cases of lung infection in the comparison group, which were brought under control after treatment with antibiotics. No deaths occurred in either group during the course of these trials.

Typical examples

Example 1

Female, 58 years old with fluid retention in left thoracic cavity. About 600 ml of fluid with blood was extracted on the second day after entering the hospital. The adenocarcinoma could be seen from testing, and the disease was determined to be membrana pleuralis transference of carcinoma of liver. Medicinal Mushroom polysaccharide tablets were added to the FM plan, and continued administration after chemotherapy. The symptoms of respiratory tract were relieved, and the water retention in the thoracic cavity was controlled. The patient's condition was stable and only a loss of hair was noted. She added 1 kg to her body weight and her KPS score increased by 60. On retesting the hemogram, white blood cell count was 3.8 x 109/L, and the functions of liver and kidneys were normal.

Example 2

Male, 69 years old with carcinoma of right lung. He entered the hospital for abdominal pain after chemotherapy of 2 months and radiotherapy of 1 month. The disease was very aggressive with anemia, and his KPS score was 40. Medicinal Mushroom polysaccharide tablets were added to the FM plan, and continued with the conventional therapy. The abdominal pain was relieved, the appetite was improved, overall condition was much improved.

Discussion

1. The mixed polysaccharide was extracted from 6 edible and medicinal fungi. It was shown in this trial that the mixed polysaccharides can inhibit the protein synthesis of cancer cells, change the physiological condition of cancer cells, inhibit the growth and transference of cancer cells, relieve the poisoning action of the anti-cancer drugs, improve the patients sleep and appetite and result in overall improvement of the symptoms.
2. The mixed polysaccharides have an apparent role in controlling and improving the immunity. After taking the tablets, nonspecific immunity of the body is enhanced, improvements in the secretion of IGA, increase in the function of monocyte-macrophage and in the activity of NK cells, and in keeping the immunological balance and stability of the body.
3. The mixed polysaccharide has antagonistic action for the complications caused by the use of the anti-tumor drugs and the White Blood Cell reduction caused by various reasons of clinical therapy.
4. The main material of Polyactin-A used by the comparison group is gluco-mannosan peptide. This is a highly effective pharmaceutically available immune enhancement drug. It can enhance the immunity and activate the function of phagocytes and white blood cells. It is used for treatment of the reduction in white blood cells seen during cancer treatment using radiotherapy and chemotherapy. (See footnote)
5. The results shown during this trial from the treatment of cancer patients indicate that the mixed polysaccharides of Medicinal Mushrooms has an apparent role in the treatment of all kinds of cancer, protecting the haematopoiesis function of the bone marrow, inducing the action of the digestive tract, increasing the immunity of the cells, increasing the activity of the NK cells, the LAK cell and the ratio of the Th/Ts cells. The curative effect of this polysaccharide mixture is higher than that of Polyactin A, and has an excellent helper role as an adjunct for the treatment of tumor patients.

References

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Footnote

Polyactin-A is a clinically used drug in China for reducing the incidence of side effects in the treatment of Cancer. This drug is not yet widely known in the west. It is thought by many doctors to be the strongest Immune Enhancement drug yet discovered. Clinical trials in America are usually conducted against a placebo. In other words, half of the trial group gets sugar pills and half get the effective medication. In China, this practice is considered unethical and inhumane. Instead, when a new medication shows enough promise to warrant clinical trials, the new one is tested against the very best medication available. In this trial, **Immune Fx** was tested against, and showed greater effectiveness in reducing side effects than Polyactin-A.