

## Intriguing and Varied Effects in Humans from Consumption of a Novel, Patented Botanical Blend

Getting adequate sleep, eating a balanced diet, regular exercise, and managing stress are important lifestyle management strategies to maintain a well-functioning immune system. But is there anything else you can do to counteract the constant barrage of attacks to your immune system brought about by stress, pollution, aging, and even every day metabolic processes?

Perhaps there is. A novel botanical blend has been shown in recent clinical studies to enhance and strengthen the body's natural defense systems. Apparently, this blend was selected from over 200 different herbs for their ability to induce interferon production, a key component of effective immune system response.

Individual ingredients in the immune boosting blend include **pumpkin seed** (*Cucurbita Moschata*) extract, which has been reported to induce interferon in cell cultures. It also contains **Plantago seed** (*Plantago asiatica*), which has polysaccharides thought to stimulate non-specific immunity. **Safflower flower** (*Carthamus tinctorius*) polysaccharides have been shown experimentally to prompt macrophages to produce cytokines. And **Japanese Honeysuckle** (*Lonicera japonica*) flower buds have been traditionally used to fight infections. Experimentally, it's been reported to increase the activity of immune cells.

Recent research is starting to elucidate the potential benefits of this immune-boosting botanical blend in humans. For example, clinical studies demonstrate that this novel, patented botanical blend is effective at inducing the body's natural production of interferon, a key conductor and activator of immune response processes. Experimental studies have shown the patented blend activates and increases the phagocytic activity of macrophages and may increase the activity of natural killer cells, immune system defenders that seek out and destroy invaders at the cellular immune response level.

### Human Clinical Trials

#### I. Administration of a Botanical Blend in Patients with Chronic Hepatitis C<sup>1</sup>.

High dose interferon is approved as a treatment for hepatitis C

It is significant that the botanical blend decreased the plasma FSH level and appears to have stimulated myelopoiesis through the cytokine system, thereby reducing menopausal symptoms in postmenopausal women. The authors propose that in postmenopausal women, this botanical blend may have acted as an immunomodulator and an endocrine modulator.

#### 5. Administration of a Patented Botanical Blend on Physical and Mental Symptoms Accompanying Premenstrual Symptoms (PMS)<sup>5</sup>.

Clinical effects of the patented botanical blend were measured on PMS symptoms accompanying menstruation. Forty-two women ages 20-35 years old presenting with PMS symptoms took 800 mg daily of the blend for 3 months reported statistically significant improvements for abdominal cramps, low back pain, swollen breasts, acne, breast pain, constipation, nervousness, sleepiness, short temper, and reduction of concentration after one month.

Study results suggest administration of the herbal blend may be effective in improving some physical and mental symptoms associated with PMS. As this test was an uncontrolled study, randomized placebo controlled testing is warranted.

#### References

1. Kaji, S. Yoshida, N. Nagata, T. Yamashita, E. Mizukoshi, M. Honda, Y. Kojima and S. Kaneko: An Open-Label Study of Administration of EH0202, a Health Food Additive, to Patients with Chronic Hepatitis C. *Journal of Gastroenterology*. 2004; Sep;39(9):873-8.
2. Studies with pollenosis formula including an open-labeled trial with allergy patients at Yamanashi Medical University, Japan, June 2000 (Unpublished)
3. T. Ushiroyama, S. Yoshida, and K. Tadaki: Clinical Efficacy of EH202, a Kampo Formula on the Health of Middle-Aged Women. *American Journal of Chinese Medicine*. 2004;32(5):755-70.
4. T. Ushiroyama, S. Yoshida, K. Tadaki, A. Ikeda and M. Ueki: A pilot study of a Kampo formula, EH0202, with intriguing results for Menopausal symptoms. *Journal of Alternative and Complementary Medicine*. 2004 Apr;10(2):397-9.
5. M. Kubo, Y. Hashimoto and S. Yoshida: The effect of health food containing EH0202 on physical and mental symptoms accompanying menstruation in women with premenstrual syndrome (PMS). *Clinical Pharmacology and Therapy*. 2004;14(2):129-142.



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but has the disadvantage of high cost and severe side effects. The investigators in this study chose to look at the novel botanical blend for its potential natural interferon induction and the impact on patients with chronic hepatitis C.

The three month study conducted at Kanazawa University Hospital in Ishikawa, Japan, was an open-label trial of patients with chronic hepatitis C who ingested the equivalent of 1g of the blend daily. Of the 35 patients that completed the study, there were improvements reported in malaise, abdominal bloating, nausea, and vomiting with no adverse changes in hematology or biochemical examination parameters. There was a statistically significant decrease in HCV-RNA virus levels in patients with high viral titers after 1 and 3 months administration of the patented botanical blend and no serious adverse events were observed with botanical blend administration.

Although larger scale controlled trials need to be conducted, the study findings suggest that the botanical blend has anti-viral activity and may be both safe and useful for administration to patients with chronic hepatitis C, especially in those with high viral titers.

## **2. Administration of a Patented Botanical Blend in Patients with Pollenosis<sup>2</sup>.**

Allergies such as hay fever are hypersensitivities in which immune responses to environmental antigens cause inflammation and damage to the body itself. Hay fever, for example, is an IgE antibody-mediated hypersensitivity that initiates a local inflammatory response. The investigators of these trials studied the botanical blend containing pumpkin seed extract because pumpkin seed has reportedly been shown to suppress IgE antibody production in Chinese medicine.

Three uncontrolled trials on 113 subjects with mild nasal allergy or hay fever were conducted between 1998 and 2000. In these trials, subjects who used the botanical blend reported specific improvements in subjective measurements such as sneezing, nasal discharge, teary eyes, and nasal blockage. Still others reported improvements in overall conditions related to nasal allergies following administration.

In a controlled trial conducted at Yamanashi Medical University, Japan, 10 subjects with nasal allergy consuming 2 g daily of the botanical blend for 4 weeks showed a statistically significant increase in peripheral blood gamma interferon levels after 4 weeks when compared to the pre-treatment measurement. Eight subjects taking placebo showed no such improvement.

## **3. Effect of Administration of a Botanical Blend in Menopausal Women<sup>3</sup>.**

Biological factors including hormones and cytokines, as well as psychological factors are known to be important factors in determining expression of menopausal symptoms. The negatives associated with hormone replacement therapy are driving the search for alternative therapies and some traditional Japanese Kampo medicines have shown promise for improving some symptoms associated with menopause.

Thirty-two postmenopausal women were given 2 g daily of the botanical blend for 6 months to measure effects on the immune and endocrine systems using Greene's Climacteric Scale, the Visual Analog Scale, and other biomarkers in a study conducted at Osaka Medical College, Osaka, Japan. There was a significant decrease in Greene's Climacteric Scale and VAS scores, significant decrease in systolic and diastolic blood pressure, significant decrease in facial skin surface blood flow, and a significant decrease in plasma TG and LDL-cholesterol after 3 months administration.

The novel botanical blend appears to have clinically improved menopausal symptoms in postmenopausal women and may help to maintain or improve normal biological function and quality of life as measured by these indicators in postmenopausal women.

## **4. Some Effects of a Botanical Blend on Menopausal Symptoms<sup>4</sup>.**

In a follow up to the previous study, there was a significant decrease in plasma FSH level, and a significant increase in plasma GM-CSF levels and after 6 months administration of the botanical blend in the 32 subjects.