

Clinical study of the effects of immutonic capsule on blood immune parameters in human volunteers

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ABSTRACT

Introduction: Many herbs and natural food materials have been historically recognized as an effective panacea that can establish a balanced inflammatory response and promote healthy immune response as well as have antibacterial and viral effects. The clinical use of some medications can cause serious side effects. We propose that natural ingredients could serve as food supplement immune tonic with antibacterial & antiviral properties that serve as a better prophylactic and therapeutic approach against COVID-19 and others infections.

Objective: The study aimed to evaluate the effect of immutonic capsule on blood immune parameters in human volunteers.

Methods: Twenty-four male and female adult volunteers, aged between 24 and 65 years were selected for the study.

Conclusion: The incidence of SSI after orthopedic procedures is high which emphasizes the importance of continuous surveillance and implementation of infection control measures to contain the problem.

Study design: The study had randomized clinical trials. Volunteers were taken immutonic capsule three times daily after meal for one week. Blood immune parameters count blood cell (total white blood cells, total red blood cells, hemoglobin, platelets and C-Reactive protein were tested before and after taken IMMUTONIC capsule.

Results: Total White Blood Cells count and its differential counts, neutrophils, lymphocytes and monocytes were significantly increased, also, total Red Blood Cells count and hemoglobin were significantly increased within normal range, but platelets count were non-significant changes after 7 days. On other hand, C-Reactive protein was significantly decreased after 7 days of treatment at $p < 0.05$.

Conclusion: The present study indicated that immutonic capsule significantly boost and enhance immune system and had anti-inflammatory effects which can be used as better prophylactic, boosting immunity and therapeutic against COVID-19 and others infections.

Key words: Immutonic capsule, natural, food, immune system, anti-inflammatory, COVID-19

Introduction

Many food ingredients like *Nigella sativa* seed have been historically recognized as an effective panacea that can establish a balanced inflammatory response and promoting healthy immune response. Garlic, ginger and black pepper are used as food supplements in India during the time of infectious diseases. Literature shows that they have anti-inflammatory effects [1]. Many studies showed both prophylactic and curative effects against Chikungunya during the epidemic in Kerala from 2006-09. Chikungunya, a mosquito transmitted viral fever spread widely in Kerala. This disease was identified as chikungunya in the affected patients by laboratory tests in the Government hospitals. The patients had fever and joint pains in the body. The authors made a preventive food supplement against chikungunya. The authors along with the above physicians made a press conference at Kottayam in 2006 and requested the public to take food supplement daily to prevent chikungunya [1].

The action of the supplement is due to the effect of poly sulfides and terpenes which dilate the blood vessels and increase blood circulation and excretion of toxins. Second aspect is to stimulate lymphocytes for immune action against the virus and the third one is to counteract the inflammatory actions of prostaglandins by decreasing its synthesis and actions by compounds like ajoene. Here the nutraceuticals present in the ingredients of the food supplement worked both prophylactically and curatively against the viral fever.

Stimulating [2] immune cells such as T and Natural killer cells and macrophages effects [3] of garlic, anti-inflammatory [4] and related effects of black pepper [5], anti-inflammatory [6] and anti-clotting effects of ginger [7] have been reported by many workers. These principles are known as nutritional food supplements or nutraceuticals that give protection to our body from many diseases. Therefore, these and related food materials have medicinal potential and they form the common ingredients for the indigenous system of medicines in India, Yemen, China and elsewhere. More than 199 countries worldwide are affected by a new coronavirus disease (COVID-19) caused by infection with SARS-CoV-2. The transition from early symptoms to acute respiratory distress syndrome (ARDS) is most likely due to uncontrolled cytokine release. There is an urgent need to identify safe and effective food supplement to boosting immune system. However, the clinical use of some medications can cause serious side effects [8]. We proposed that natural food supplements like that could serve as a better prophylactic, boosting immunity and therapeutic approach. Our study aimed to evaluate the clinical effect of immutonic capsule which contain mixture of six natural food materials/ingredients as immune tonic action in human volunteers.

Methods

The hypothesis of new formulation of IMMUTONIC capsule contain 500 mg mixture of six natural food materials/ingredients with different amounts for each one which was done by Prof. Dr. Hussien O. Kadi (Patent).

Twenty-four male and female adult volunteers, aged between 24 and 65 years were selected for the study. The volunteers were free from significant cardiac, hepatic, renal, pulmonary, gastrointestinal, neurological or hematological disease as determined by way of medical histories and physical examinations. All volunteers gave a written informed consent and the Ethics Committee of Yemen University, Faculty of medical Sciences approved the clinical protocol and the study had been performed in accordance with the ethical standards as laid down in the 1964 Declaration of Helsinki and its later amendments or comparable ethical standards. The study had a randomized clinical trials for one week.

Study design

Volunteers took immutonic capsule three times daily after meal for one week. Blood immune parameters count blood cell (total White Blood Cells, neutrophils, lymphocytes, monocytes total Red Blood Cells, hemoglobin, platelets and C-Reactive protein) were tested before and after taken immutonic capsule. Statistics for parameters levels before and after treatment were compared using the paired t-test. Differences were considered significant when P values were less than 0.05. All data were analyzed with SPSS statistical software.

Results

As shown in table 1, total White Blood Cells count and its differential counts, neutrophils, lymphocytes and monocytes were significantly increased, also, total red blood cells count and hemoglobin were significantly increased within normal range, but platelets count were non-significantly changed after 7 days. On other hand, C-Reactive protein was significantly decreased after 7 days of treatment.

Table (1): Effect of immutonic capsule in a dose of one capsule three times daily for one week on blood immune system parameters in human volunteers. (N: 24, M± SD).

Blood Immune Parameters	Blood Immune Parameters Level (M± SD)		P- value
	Before (Low-High)	After (Low-High)	
Total WBCs count 10 ⁹ /L	6.22±2.86 (3.7 – 12,0)	6.8±2.49 (4.00-11.79)	0.014
Neutrophils %	46.64±8.06 (33-62.5)	49.58±8.63 (37- 71.2)	0.04
Lymphocytes %	36.97±7.22 (26-55)	40.51±7.95 (26-55)	0.04
Monocytes %	5.63±2.06 (1-9)	6.68±2.50 (4-10)	0.004
C-Reactive Protein mg/L	8.80±5.66 (1-22)	2.64±2.73 (0.2-12)	0.000
Hemoglobin g/dl	13.38±2.95 (8.7-17.6)	14.00±1.65 (9.1-17.2)	0.005
Total RBcs 10 ¹² /L	4.75±0.58 (3.9-5.7)	5.03±0.33 (4.7-5.7)	0.003
Platelets count 10 ⁹ /L	297.66±36.68 (261-436)	296.83±51.12 (261-422)	0.924

Total WBC count from (6.22±2.86) at zero day to (6.8±2.49), neutrophils (46.64±8.06) to (49.58±8.63), lymphocytes (36.97±7.22) to (40.51±7.95), monocytes (5.63±2.06) to (6.68±2.50), total red cells count (4.75±0.58) to (5.03 ± 0.33), hemoglobin (13.38±2.95) to (14.00±1.65) significantly increased at P < 0.5 and platelets count (297.66±36.68) to (296.83±51.12) non significantly changes at P = 0.924 after 7 days. C-Reactive protein was significantly decreased from (8.80±5.66) to (5.03±0.33) at P<0.05 after 7 days of taken IMMUTONIC capsule three times daily after meal.

Discussion

Many therapeutic effects of herbs and food materials/ingredients have been suggested due to their wide array of immunomodulatory effects and influence on the immune system of the human body. Phytochemicals such as flavonoids, polysaccharides, lactones, alkaloids, diterpenoids and glycosides, present in several herbs and food materials/ingredients, have been reported to be responsible for the immunomodulating properties. Many reviews reported that herbs and food materials/ingredients derived compounds (curcumin, resveratrol, epigallocatechol-3-gallate, quercetin, colchicine, capsaicin, andrographolide, and genistein) which have exhibited potent effects on cellular and humoral immune functions and have been identified over the years for their immunomodulatory characteristics. Numerous illnesses can be alternatively treated by immunomodulation using medicinal plants, instead of chemotherapy [9]. Therefore, it is an essential need to use some of the traditional medicines and combine the modern drug to inhibit the viral activity [10].

H O. Kadi [11] reviewed that garlic, onions, black bean, ginger, black and green pepper, which have an anti-virus effect [12][13][14][15].

The present study shows that Immutonic capsule significantly increased total White Blood Cells count and its differential counts, neutrophils, lymphocytes and monocytes of human volunteers after 7 days. These results shows that total WBCs in human volunteers which were less than normal got elevated to normal counts. This study suggests that Immutonic capsule boosting immune system and have immunomodulating properties.

All reviewed studies demonstrated that supplementation or treating patients with *N. sativa* seed alleviates symptoms of allergic rhinitis and decreases the body temperature in allergic patients. These effects may be related to different immunomodulatory properties of the plant including enhancing the phagocytic and intracellular killing activities of PMN and increment of CD8 counts as well as antihistaminic activities of *N. sativa* lipidand water-soluble constituents. Bronchodilatory, antiinflammatory, antioxidant and immunomodulatory effects, *N. sativa* and its constituents may be regarded as an effective remedy in allergic and obstructive lung diseases as well as other respiratory diseases as a preventive and/or relieving therapy [16].

Scientific research have shown that Black pepper, Curcuma and Ginger increase the body resistance to infections. Curcuma is one of the strongest antioxidants with very strong anti-inflammatory, antiviral, antibacterial, anti-cancer, antioxidant and antiseptic properties. The main pharmacological activities of Ginger and compounds extracted from its rhizome include immunomodulatory, anti-cancer, anti-inflammatory, analgesic and antiemetic activities [17][18][19][20][21][22][23].

On other hand, this study shows significant increase in total red cells count and hemoglobin level.

Iron is a fundamental element for normal development of the immune system. Its deficiency affects the capacity to have an adequate immune response. The role of iron in immunity is necessary for immune cells proliferation and maturation, particularly lymphocytes, associated with the generation of a specific response to infection. Humoral, cell-mediated and nonspecific immunity and the activity of cytokines which have an important role in various steps of immunogenic mechanisms are influenced by iron deficiency anemia. If you are anemic, you do not have enough oxygen-binding hemoglobin.

Is it accurate to relate the more serious responses to COVID-19 to an overactive immune? Because low hemoglobin will ultimately lead to poor immunity. Iron plays an important role in body defense and is essential for normal immune system development where its deficiency may results in an inadequate immune response. IDA is associated with impaired cell-mediated immune response specifically T-cell mediated immunity [24][25][26][27].

Immutonic capsule reported significant and very well increased appetite which improves feeding reflecting in general health [28].

This study also, shows significantly decrease of C-Reactive protein level after 7 days of taken Immutonic capsule which reflecting its effect as anti-inflammatory.

C-reactive Protein (CRP) level has widely replaced Erythrocyte Sedimentation Rate (ESR) as a marker of inflammation, infection, and tissue damage. CRP binds to phosphocholine on micro-organisms. It is thought to assist in complement binding to foreign and damaged cells and enhances phagocytosis by macrophages (Opsonin-mediated phagocytosis), which express a receptor for CRP. It plays important roles in inflammatory processes and host responses to infection including apoptosis, phagocytosis, nitric oxide (NO) release, and the production of cytokines, particularly interleukin-6. It plays a role in innate immunity as an early defence system against infections. At the early stage of COVID-19, CRP levels were positively correlated with lung lesions. CRP levels could reflect disease severity and should be used as a key indicator for disease monitoring [29][30][31].

Maiti S et al. [32], (2020) reported that Nigellidine has hepato/reno-protective, immunomodulatory/anti-inflammatory and antioxidant activities as well as it inhibits important proteins of COVID-19. Antiviral of garlic, antiviral, anti-inflammatory and related effects of black pepper, anti-inflammatory and anti-clotting effects of ginger have been reported by many workers. The biological actions of garlic principles have been attributed to its poly sulfides which react with SH groups free radicals and also stimulants immune cells such as T and Natural killer cells and macrophages. Ginger contains many terpenes and their derivatives such as zingiberene, beta-bisabolene, sesquiphellandrene, gingerol, zingerone and shogaols. Black pepper contains terpenoids like alpha-pinene, sabinene, beta caryophyllene, delta-3-carene, limonene and beta pinene. In addition to these, it contains an alkaloid piperine also. These principles are known as nutritional medicines or nutraceuticals that give protection to our body from many diseases. Therefore, these and related spices have medicinal potential and they form the common ingredients for the indigenous system of medicines in India, China and elsewhere [33][34][35][36][37].

This study shows that immutonic capsule can be used as prophylactic, treatment of mild and moderate COVID-19 and others infections via boosting immunity, elevation of hemoglobin, improving the feeding, anti-inflammatory and anti-bacterial & viral effects through its compounds like thymoquinone.

Conclusion

The present study indicated that Immutonic capsule significantly boost and enhance immune system and had anti-inflammatory effects which can be used as better prophylactic, boosting immunity and therapeutic aspects against COVID-19 and others infections.

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