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Research Article

Clinical Study of the effects of Immutonic capsule in human volunteers with flu symptoms

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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 promoting healthy immune response as well as have antibacterial and viral effects. The clinical use of some medications can cause serious side effects. We proposed that natural ingredients could serve as a better therapeutic approach.

Objective: The study aimed to evaluate the effect of IMMUTONIC capsule in human volunteers with flu symptoms.

Methods: Twenty-four male and female adult volunteers, aged between 21 and 60 years were selected for the study.

Study design: The study has a randomized clinical trials for one week. Volunteers were taken IMMUTONIC capsule three times daily after meal for one week. Improving of Flu symptoms were follow up after 3 days and 7 days using improving health scale 0-5.

Results: flu symptoms and appetite were significantly improving after 3 days of follow up at p < 0.05, while after 7 days were highly significant improving health at p < 0.05.

Conclusion: The present study indicated that Immutonic capsule improves Flu symptoms via improved immune system and its antibacterial & viral effects as well as increased appetite which lead to good feeding.

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 as well as have antibacterial and viral effects. Garlic, ginger and black pepper are used as food supplements in India during the time of infectious diseases. Literature shows that they have antiviral and anti-inflammatory effects [1]. Many studies showed both prophylactic and curative effects against Chicungunya during the epidemic in Kerala form 2006-09. Antiviral [2] and stimulate immune cells such as T and Natural killer cells and macrophages effects [3], of garlic, antiviral, 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 else where. More than 199 countries worldwide are affected by a new coronavirus disease (COVID-19) caused by infection with SARS-CoV-2gh21. 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 drugs for treatment. 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.

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Our study aimed to evaluate the clinical effect of Immutonic capsule which contain mixture of six natural food materials/ ingredients as immune tonic and antibacterial and viral action in human volunteers.

Methods

The hypothesis of new formulation of IMMUTONIC capsule contain 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 21 and 60 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, physical examinations. All volunteers gave a written informed consent and the Ethics Committee of Yemen University, Faculty of medical Sciences approved the clinical protocol. The study had a randomized clinical trials for one week.

Study design

The study has a randomized clinical trials for one week. Volunteers were taken IMMUTONIC capsule three times daily after meal for one week. Improving of Flu symptoms were follow up after 3 days and 7 days using improving health scale 0–5. Statistics Scores for the flu symptoms 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 flu symptoms and appetite were significantly improving after 3 days of follow up at p <0.05, while after 7 days were highly significant improving health at p < 0.05 Table 1.

Table 1: Effect of IMMUTONIC capsule in a dose of one capsule three times daily for one week in volunteers with Flu symptoms. (N: 24, M±SD).

Symp.	Patients symptoms Improving (M±SD)			P - Valua
	Zero day	3 days	7 days	F - Value
Headache	0.00 ± 0.00	3.30 ± 0.73	4.6 ± 0.51	0.001
Fever	0.00 ± 0.00	3.45 ± 0.05	5.0 ± 0.51	0.001
Weak	0.00 ± 0.00	2.68 ± 0.47	4.57 ± 0.51	0.001
Cough	0.00 ± 0.00	3.21 ± 0.48	4.47 ± 0.51	0.001
Maylgia	0.00 ± 0.00	2.68 ± 0.47	4.39 ± 0.51	0.001
sinusitis	0.00 ± 0.00	2.68 ± 0.47	4.39 ± 0.51	0.001
Smell	0.00 ± 0.00	0.75 ± 0.42	4.3 ± 0.48	0.001
Taste	0.00 ± 0.00	0.42 ± 0.51	3.4 ± 0.52	0.001
Appetite	0 00 + 0 00	500 ± 000	500 ± 000	0.001

Headache from (0.00 ± 0.00) at zero day to (3.30 ± 0.73) , weak to (2.68 ± 0.47) , cough to $(3..21 \pm 0.48)$, myalgia to (2.68 ± 0.47) , sinusitis to (2.68 ± 0.47) , smell to (0.75 ± 0.42) and taste to (0.42 ± 0.51) at P<0.05, while after 7 days high scores of health improving scale significantly as compared with scores after 3 days of treatment (4.6 ± 0.51), (4.57 ± 0.51), (4.47 ± 0.51), (4.39 ± 0.51), (4.39 ± 0.51) respectively at P<0.05. Smell and taste were significantly scores improving to (4.3 ± 0.48) and (3.4 ± 0.52) respectively. On other hands, appetite highly significant scores improving at 3 days and 7 days (5 ± 0.00) at P<0.05.

Discussion

Influenza virus is capable of causing respiratory diseases worldwide. This virus is constantly evolving and new antigenic variants give rise to epidemics and pandemics. Influenza virus is unique among respiratory tract viruses because of its considerable antigenic variations. These mutations make it extremely difficult to develop effective vaccines and drugs against the virus [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].

The present study shows that Immutonic capsule significantly improves Flu symptoms after 3 and 7days as well as significantly improves appetite.

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

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 has shown that Black pepper, Curcuma and Ginger increase the body's resistance to infections. These three spices contain substances with a broad spectrum of antimicrobial activity. They are also a rich source of natural antioxidants that neutralize free radicals. Black pepper has antiemetic, antibacterial and antipyretic effects. Curcuma is one of the strongest antioxidants with very strong anti-inflammatory, antiviral, antibacterial, anticancer, antioxidant and antiseptic. The main pharmacological activities of Ginger and compounds extracted from it's rhizome include immunomodulatory, anti-cancer, anti-inflammatory, analgesic and antiemetic activities [17–23].

The present study suggests the clinical effect of Immutonic capsule via; immunomodulatory/anti-inflammatory , antioxidant and antibacterial and viral activities as well as very well increased appetite which improves feeding reflecting in general health.

Maiti S, et al. (2020) [24], reported that Nigellidine has hepato/reno-protective; immunomodulatory/antiinflammatory 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, antiinflammatory and anti clotting effects of ginger have been reported by many workers. The biological actions of garlic

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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 else where [25-29].

Conclusion

The present study indicated that Immutonic capsule improves Flu symptoms via improved immune system and its antibacterial & viral effects as well as increased appetite which lead to good feeding and used as better prophylactic, boosting immunity and therapeutic.

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