Advances in Pharmacology and Therapeutics Journal
Shahid Sadoughi University of Medical Sciences, Yazd, Iran

SHAHID SADOUGHI UNIVERSITY OF MEDICAL SCIENCES

Clinical Trial

Evaluation of the Effectiveness of Ivermectin in Combination With Standard Treatment in Suspected COVID-19 Patients: A Double-Blind Randomized Clinical Trial

Running Title: Ivermectin Efficacy COVID-19

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ARTICLEINFO

Received: 01/08/2025
Accepted: 08/20/2025

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Abstract

Background: The 2019 coronavirus is a highly contagious viral disease that causes acute respiratory syndrome and has a catastrophic impact on the world's demographics. Ivermectin may be associated with inhibition of nuclear transport, a mechanism that may be effective against SARS-CoV-2. In this study, we investigated the effectiveness of ivermectin in combination with standard treatment in suspected or probable COVID-19 patients.

Materials and Methods: This study was a prospective and double-blind randomized controlled clinical trial. This study was conducted on 50 patients aged 18 to 60 (25 in the intervention group and 25 in the control group) suspected of having COVID-19 based on clinical symptoms, blood oxygen percentage, and COVID PCR, who are candidates for outpatient treatment. Patients are randomly divided into two intervention groups, including ivermectin and standard treatment, and a control group, including placebo and standard treatment. Standard treatment includes 500 mg acetaminophen tablets and diphenhydramine syrup. The patients in the ivermectin group used oral ivermectin at a dose of 200 µg/kg once a day for two days in addition to the standard treatment. The patients were contacted on the first, third, seventh, and fourteenth days, and the symptoms were asked according to the questionnaire. In this study, the data was statistically analyzed using SPSS 22 software.

Results: Comparison of NYHA (New York Heart Association) classes between the first day and the fourteenth day using the Wilcoxon test showed that the NYHA classes in the fourteenth group had a significant decrease compared to the first day, and the effect of the group was also significant ($P \leq 0.05$). Changes in cough frequency between the two groups during 14 days were statistically significant ($P \leq 0.05$). Changes in the frequency of shortness of breath between the two groups during 14 days were statistically significant ($P \leq 0.05$). Changes in the frequency of fever, headache, dizziness, myalgia, and the need to receive painkillers between the two groups during 14 days were not statistically significant. Changes in the frequency of nausea and vomiting between the two groups during 14 days were statistically significant ($P \leq 0.05$).

Conclusion: In the end, we concluded that using ivermectin in patients with mild to moderate clinical conditions of COVID-19 effectively improved the clinical symptoms of patients who were also receiving standard treatment, and patient's symptoms improved in a shorter period. These findings can help specialists choose multidrug treatment, including ivermectin, in treating respiratory diseases such as COVID-19.

Keywords: COVID-19, Ivermectin, Shortness of Breath, SARS-CoV-2

Citation: Akhoundimeybodi Z, Heidari F, Nikoonezhad M, Mousavinasab SR, karimzadeh I, shamsi F, Astani A. Evaluation of the Effectiveness of Ivermectin in Combination With Standard Treatment in Suspected COVID-19 Patients: A Double-Blind Randomized Clinical Trial. Adv Pharmacol Ther J. 2025;5(2): 82-89

Introduction

The 2019 coronavirus disease is a highly contagious viral disease that causes acute respiratory syndrome and has had a catastrophic impact on the world's demographics, leading to the death of more than 6 million people worldwide by March 2022. This disease became the most important global health crisis after the 1918 influenza pandemic. Factors affecting the mortality rate include age, underlying conditions, and disease severity, which differ significantly between countries (1-3).

Coronaviruses are single-stranded, enveloped RNA viruses with a diameter of 80-120 nm and are divided into four groups: alpha, beta, delta, and gamma. Before the identification of COVID-19, only six types of coronaviruses could infect humans, and COVID-19, a member of the beta-coronavirus family, is the seventh of them. Coronavirus has four main structural proteins named S (Spike), E (Envelope), N (Nucleocapsid), and M (Membrane).

Through the Receptor-Binding Domain (RBD) located in the Spike protein, COVID-19 uses Angiotensin-converting enzyme-2 (ACE2) as a receptor. It infects cells with ACE2. The ACE2 receptor is abundantly found in alveolar cells, cardiac myocytes, and vascular endothelial cells. Due to the high binding affinity of COVID-19 to ACE2, the number of viruses that infect cells is higher than other coronaviruses. ACE2 protein is also effective in the physiology and pathology of the reproductive system, including testes and ovaries. In this way, COVID-19 probably affects the production of sperm and reduces its number, and it also affects the production of sex hormones and can lead to a decrease in sexual desire(4).

According to recent reports, the most common symptoms at the onset of the disease include fever, fatigue, dry cough, shortness of breath, and body pain, and other symptoms include headaches, smell and hearing disorders, nausea, and vomiting. A few patients initially reported only gastrointestinal symptoms such as diarrhea and vomiting, and some people also reported a disorder of taste and smell. There is no specific treatment approved by the US Food and Drug Administration (FDA) for COVID-19. The effectiveness of any drug has not been proven. The drug therapies that have been used so far include Remdesivir, Recigen, Chloroquine, Hydroxy Chloroquine, Lopinavir/Ritonavir, Favipiravir, Azithromycin, Tocilizumab, Sarilumab, Corticosteroids, Pulmonary dilators like nitric oxide, Non -steroidal anti-inflammatory drugs, Bronchodilators (5). A recent in vitro study showed that ivermectin is active against cells infected with COVID-19 (6).

Ivermectin is an antimicrobial drug that treats parasitic and viral infections, including HIV, influenza, dengue fever, and Zika virus. The anti-parasitic and antiviral mechanisms of ivermectin are different from each other. Ivermectin shows high binding affinity to viral S protein and human cell surface receptors ACE-2. Ivermectin is placed between the viral spike and the ACE-2 receptor. This is achieved through its high affinity for the SARS-CoV S1 protein, which potentially limits binding to ACE-2 receptors or sialic acid receptors and prevents viral cellular entry (7-9).

  DOI: https://doi.org/10.18502/aptj.v5i2.19457

Materials and methods

This clinical trial study was conducted on patients suspected of having COVID-19 based on clinical symptoms, O2SAT, and PCR Covid who are candidates for outpatient treatment. In previous researches, no complete studies can reliably calculate the sample size. However, we want to reduce the overall improvement score obtained from the patient's symptoms by 2 points, taking into account the maximum standard deviation. In that case, a score equal to 2.5 was calculated, and the number of 25 patients was required for each group. The significance level is 5%, and the test power is 80%. he sampling method was random.

$$= \frac{(Z_{(1-\frac{\alpha}{2})} + Z_{1-\beta})^2 2S^2}{(\mu_1 - \mu_2)^2}$$

Inclusion criteria: Age range between 18-60 years old. Outpatient treatment patients.

Exclusion criteria: Pregnant patients.

This study was conducted on 50 patients (25 in the intervention group and 25 in the control group) suspected and probable of COVID-19 based on clinical symptoms, blood oxygen percentage, and COVID PCR who are candidates for outpatient treatment. Patients were randomly divided into two intervention groups, one including ivermectin and standard treatment, and a control group, one including placebo and standard treatment. At the beginning of the study, patients were randomly divided into one of two groups (25 people in each group) using permutation blocks.

Standard treatment includes 500 mg acetaminophen tablets used during fever and 10 cc diphenhydramine syrup every 8 hours to control cough. The patients in the ivermectin group used oral ivermectin at a dose of 200 micrograms per kilogram of body weight once a day for two days in addition to the standard treatment. Control group patients received standard treatment and placebo. After packing the products in the envelope and obtaining the patient's consent to participate in the study, the patients are asked to use the drugs of their group for 5 days according to the established protocol. All the above steps were hidden from the eyes of the patient, doctor, and evaluators. The project manager identifies the people, puts the medicines in envelopes of the same shape for the patient, and marks them with A or B codes.

The improvement of clinical symptoms, including fever, cough, shortness of breath, side effects that occur during treatment, or severe side effects that lead to discontinuation of treatment, were evaluated. The prepared questionnaire first recorded demographic information, phone numbers, and initial symptoms of the patients. The warning signs were explained to the patients, and a pamphlet containing those contents was delivered to them.

The patients were contacted on the second, third, seventh, and fourteenth days, and their symptoms were asked according to the questionnaire. Other questions included the amount of acetaminophen used to reduce fever, the reduction of shortness of breath by asking the rate of shortness of breath and its relationship with their activity level, the evaluation of the reduction of cough, and the need to refer again.

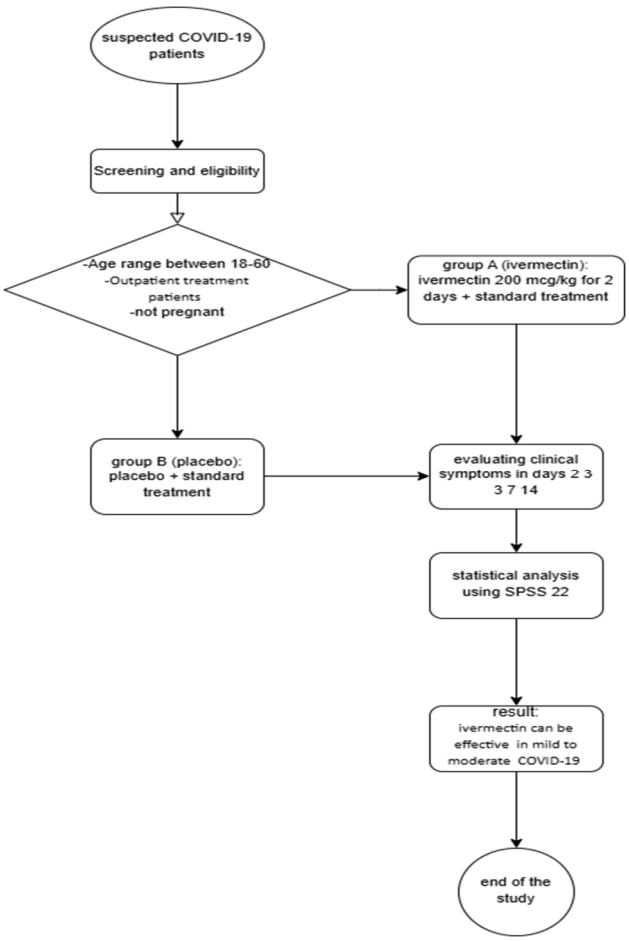
Statistical analysis

After collecting and coding the data, this study was subjected to statistical analysis using SPSS 22 software. Mean (and standard deviation) and frequency (and percentage) were used to describe quantitative and qualitative variables, respectively. Fisher-Exat and Chi-Square tests were used to compare frequency distributions, and T-test was used to compare means. In all cases, P-value<0.05 was considered as a significant level.

Results

This study was conducted on 50 patients who were candidates for outpatient treatment. The patients were divided into two groups **fig 1**.

Figure 1. Flow diagram of the study



From the ivermectin group, two people did not want to continue the study, 23 people were in this group, four people were excluded from the study in the placebo group, and 21 people were included in the study. In this study, 13 people (29.5%) were men and 31 (70.5%) were women. The average age of the patients was 48.43 ± 7 years, and the average BMI was 22.9 ± 2.88 Kg/m2.

In the ivermectin and placebo groups, 15 (65.2%) and 16 (76.2%) were women, respectively. The gender comparison between the two groups using the chi-square test showed that gender had no significant relationship with the type of treatment (P≥0.05).

The frequency of diabetes and blood pressure in the group treated with ivermectin was equal to 9 people (39.1%) and 5 (21.7%), respectively. In the group treated with placebo and standard treatment, it was equal to 9 people (42.9%) and three people (14.3٪), respectively.

Comparing the history of underlying diseases between the two treated groups using the chi-square test showed that the history of underlying diseases was not significantly related to the type of treatment (P≥0.05). The average age in the ivermectin and placebo groups was 49.5 ± 5.97 and 47.23 ± 8 years, respectively, and there was no statistically significant relationship between age and the type of treatment (P≥0.05) **Table 1.**

In the ivermectin and placebo groups, six people (26.1%) and three people (14.32%) were hospitalized, respectively, and the comparison of hospitalization between the two groups using a chi-square test showed that hospitalization has no significant relationship with the type of treatment (P≥0.05).

DOI: https://doi.org/10.18502/aptj.v5i2.19457

Table 1. Comparison of demographic variables between the two groups under study.

Variables		Ivermectin + standard treatment	Placebo + standard treatment	Chi-square test p-value
gender	man	(% 34.8) 8	(% 23.8) 5	0.32
	woman	(% 65.2) 15	(% 76.2) 16	
History of underlying disease	asthma	(% 13) 3	(% 4.8) 1	0.76
	diabetes	(% 39.1) 9	(% 42.9) 9	
	high blood pressure	(% 21.7) 5	(% 14.3) 3	
	Hypothyroidism	(% 4.3) 1	(% 9.5) 2	
	none	(% 21.7) 5	(% 28.6) 6	
age		49.5 ± 5.97	47.23 ± 8	0.088

On the first day, the frequency of NYHA classes between the two groups using the chi-square test showed that NYHA classes on the first day were not significantly related to the type of treatment (P≥0.05).

Table 2- Comparison of NYHA on the first and fourteenth day and the need for hospitalization between the two groups

Variables		Ivermectin + standard treatment	Placebo + standard treatment	Chi-square test p-value	p-value of the Wilcoxon test
hospitalization		(% 26.1)6	3 (14.3 %)	0.46	
NYHA day 1	Class 1	8 (34.8 %)	7 (33.4 %)	0.24	0.001
	Class2	11 (47.8 %)	5 (23.8 %)		
	Class3	2 (8.7 %)	5 (23.8 %)		
	Class 4	2 (8.7 %)	4 (19 %)		
NYHA Day 14	Class1	15 (65.2 %)	11 (52.4 %)	0.1	
	Class2	8 (34.8 %)	5 (23.8 %)		
	Class3	0	4 (19 %)		
	Class4	0	1 (4.8 %)		

On the 14th day, the frequency of NYHA classes between the two groups using the chi-square test showed that NYHA classes on the 14th day were not significantly related to the type of treatment (P≥0.05). Comparison of NYHA classes between the first day and the fourteenth day using the Wilcoxon test showed that the NYHA classes on the fourteenth day had a significant decrease compared to the first day, and the effect of the group was also significant (P≤0.05) **Table 2**.

Table 3. Comparison of clinical symptoms during 14 between two groups

Variables		Ivermectin + standard treatment	Placebo + standard treatment	Chi-square test p-value	p-value of the MANOVA test
Headache	first day	18 (78.3 %)	15 (71.4 %)	0.43	0.51
	third day	8 (34.8 %)	12 (57.1 %)	0.11	
	Seventh day	3 (13 %)	6 (28.6 %)	0.18	
	fourteenth day	1 (4.3 %)	2 (9.5 %)	0.46	
Fever	first day	14 (60.9 %)	17 (81 %)	0.13	0.44
	third day	8 (34.8 %)	12 (57.1 %)	0.11	
	Seventh day	2 (8.7 %)	3 (14.3 %)	0.45	
	fourteenth day	0	1 (4.8 %)	0.47	
Cough	first day	13 (56.5 %)	14 (66.7 %)	0.35	0.037
	third day	9 (39.1 %)	11 (52.4 %)	0.28	
	Seventh day	7 (30.4 %)	8 (38.1 %)	0.41	
	fourteenth day	2 (8.7 %)	4 (19 %)	0.28	
shortness of breath	first day	12 (52.2 %)	15 (71.4 %)	0.15	0.043
	third day	8 (34.8 %)	15 (71.4 %)	0.016	
	Seventh day	5 (21.7 %)	12 (57.1 %)	0.017	
	fourteenth day	3 (13 %)	10 (47.6 %)	0.014	
dizziness	first day	9 (39.1 %)	9 (42.9 %)	0.52	0.37
	third day	8 (34.8 %)	6 (28.6 %)	0.45	
	Seventh day	4 (17.4 %)	4 (19 %)	0.59	
	fourteenth day	1 (4.3 %)	2 (9.5 %)	0.48	
myalgia	first day	16 (69.6 %)	17 (81 %)	0.3	0.74
	third day	12 (52.2 %)	14 (66.7 %)	0.25	
	Seventh day	7 (30.4 %)	9 (42.9 %)	0.29	
	fourteenth day	5 (21.7 %)	11 (52.4 %)	0.18	
Nausea and vomiting	first day	5 (21.7 %)	11 (52.4 %)	0.036	0.031
	third day	7 (30.4 %)	7 (33.3 %)	0.54	
	Seventh day	0	3 (14.3 %)	0.1	
	fourteenth day	0	2 (9.5 %)	0.22	
Need to receive painkillers	first day	20 (87 %)	18 (85.7 %)	0.62	0.83
	third day	19 (82.6 %)	15 (71.4 %)	0.37	
	Seventh day	8 (34.8 %)	7 (33.3 %)	0.58	
	fourteenth day	6 (26.1 %)	7 (33.3. %)	0.42	

On the first day, the headache frequency in the ivermectin group was 18 (78.3%), and placebo was 15 (71.4%). On the third day, the headache frequency

in the ivermectin group was 14 (60.9%), and placebo was 11 (52.4%). On the fourteenth day, the frequency of headaches in the ivermectin group was 1 (4.3%) and placebo was 2 (9.5%). Comparing the frequency of headaches between the two groups using the chi-square test showed that the frequency of headaches has no significant relationship with the type of treatment comparing the frequency of headaches between the two groups on the first, third, seventh, and fourteenth days. During 14 days, the MANOVA test showed that the changes in the frequency of headaches between the two groups during 14 days were not statistically significant ($P \geq 0.05$).

The frequency of the other symptoms and their significace level are specified in **Table 3.**

Discussion

In the last two years, acute respiratory syndrome coronavirus 2 (SARS-CoV-2) has attracted tremendous attention in a short period and has accounted for significant cases and deaths. This is not the first and last time that a viral epidemic has been described as a global health emergency by WHO, so identifying the different dimensions of this disease is vital (10, 11).

Clinically, COVID-19 can range from an asymptomatic carrier state to life-threatening pulmonary involvement requiring mechanical ventilation. In diseases with a broad clinical spectrum, it is important to study different populations to understand the effectiveness of any intervention. In this study, we only selected patients with mild to moderate disease. Caly et al. showed that the viral load of SARS-CoV-2 was reduced by ivermectin in vitro. Furthermore, the ICON retrospective study showed that patients treated with ivermectin had better outcomes than those without ivermectin, even in patients with severe pulmonary involvement(12, 13).

In this randomized clinical trial, we investigated the effectiveness of ivermectin in combination with standard treatment in suspected or probable COVID-19 patients. The results of our study showed that there was no statistically significant difference in demographic variables between the two groups treated with ivermectin and standard treatment. Examination of clinical symptoms in patients during 14 days of examination showed that ivermectin significantly affected shortness of breath, cough, nausea, and vomiting compared to standard treatment. Also, comparing the NYHA status on the first day with the fourteenth day between the two groups showed that dyspnea and NYHA classification in the group treated with ivermectin significantly improved compared to the standard treatment. In contrast to the present study, Medina et al. failed to significantly improve the time to resolution of symptoms in a double-blind, randomized trial of symptomatic adults with mild COVID-19. (14). In a study by Naggie et al., among outpatients with mild to moderate COVID-19, ivermectin treatment did not significantly improve recovery time compared to placebo (15).

In Hazan et al.'s study, the efficacy of ivermectin-based multidrug therapy in patients with severe hypoxic COVID-19 was evaluated on an outpatient basis. This study showed that symptoms resolved in all subjects (on average in 11 days), and this group

  DOI: https://doi.org/10.18502/aptj.v5i2.19457

had no hospitalizations or deaths. This study showed that combination therapy is safe and effective even in outpatients with moderate to severe symptoms(16).

In another study, Gorial et al. investigated the efficacy of ivermectin as an adjunctive treatment to hydroxychloroquine and azithromycin in the treatment of hospitalized COVID-19 patients. All patients in the ivermectin group were cured compared to the control group (100% vs. 97.2%). The average length of stay in the hospital in the ivermectin group was significantly less compared to the control group (p=0.05), and no side effects were observed. The results of this study show that the addition of ivermectin to hydroxychloroquine and azithromycin is associated with better effectiveness and shorter hospitalization compared to the control group(17). Contrary to this study, in another study, Ozer et al. investigated the effectiveness of ivermectin in hospitalized patients with COVID-19. They showed that the length of stay in the intensive care unit (ICU) and the duration of mechanical ventilation were longer in the control group. There was no difference in the mortality rate with ivermectin treatment, and no difference was observed between the groups regarding length of hospital stay, ICU stay, intubation rate, and hospital mortality(18).

In another study, the effectiveness of ivermectin on more severe conditions was rejected entirely, so Lim et al. conducted a study to determine the effectiveness of ivermectin in preventing the progression of severe disease among high-risk patients with COVID-19. For all prespecified secondary outcomes, there were no significant differences between groups. Mechanical ventilation occurred in 1.7% vs. 4%, admission to the intensive care unit 2.4% vs. 3.2%, and 28-day in-hospital death 1.2% vs. 4%. Treatment with ivermectin did not prevent disease progression to a severe condition(19). The study findings do not support using ivermectin for patients with COVID-19. In the current study, the effect of ivermectin on severe cases of COVID-19 has not been investigated. In patients with COVID-19 who were visited on an outpatient basis, clinical symptoms, including shortness of breath and cough, were significantly reduced within 14 days.

Conclusion

According to the findings of the current study, the use of ivermectin in patients suffering from COVID-19 with mild to moderate clinical conditions was effective in the subsequent improvement of the clinical symptoms of patients who were receiving standard treatment. In a shorter period, the symptoms of the patients improved. These findings can help specialists choose multidrug treatment, including ivermectin, in treating respiratory diseases such as COVID-19.

Conflict of interest: No biased point of view based on the conflict of interest and personal bias of the authors has been considered in reviewing the sources and organizing the contents of this article.

Funding: No funding sources.

Acknowledgments: We thank the people who guided us in writing this article.

Ethical considerations:

IR.SSU.MEDICINE.REC.1402.019

Authors' contribution:

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  DOI: https://doi.org/10.18502/aptj.v5i2.19457