# Determining the Safety and Effectiveness of ENDOR Oral Combination Drug in the Treatment of Patients With COVID-19: A Randomized Controlled Trial

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**Abstract-** The novel coronavirus caused by SARS-CoV-2 is still a public health concern as it can have dire consequences. Anti-inflammatory drugs are promising. Therefore, this study aimed to determine the safety and effectiveness of the ENDOR oral combination drug in the treatment of patients with COVID-19. This double-blinded, randomized controlled trial was conducted at the Imam Khomeini Hospital complex in Tehran, Iran. All COVID-19 patients who were admitted to the Imam Khomeini hospital complex from April 2022 to April 2023 and who were 18-75-Year-Old signed the consent form to participate in this study, were not pregnant, and did not need mechanical ventilation at admission. In this study of 200 patients (50% in the Endor group and 50% in the placebo group), 56.8% were male, and the mean age was 65.02±14.94. There were no statistically significant differences observed between the Endor and control groups across time for temperature (*P*=.075), WBC (*P*=.095), CRP (*P*=.108), sodium (*P*=.323), or calcium (*P*=.352). The slope of the decrease in ESR and the body temperature, as well as the slope of the increase in oxygen saturation in the Endor group, was higher than in the control group. Statistically significant differences between the Endor and control groups over time for respiratory rate (*P*=.003), oxygen saturation (*P*<.001), and potassium (*P*=.031) were observed. The decreasing slope of the respiratory rate in the Endor group was significantly higher than in the control group. ENDOR with anti-inflammatory features helps COVID-19 hospitalized patients recover faster by improving oxygen saturation, lowering fever, and decreasing respiratory rate.



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## Introduction

The novel coronavirus, SARS-CoV-2, known as COVID-19 (1), remains a public health concern, as it can have dire consequences (2). Efforts have been made at vaccine development and extensive vaccination programs to limit the impact of COVID-19 (3). While vaccinations are successful in decreasing disease severity and saving hospitalizations and deaths (4), their distribution and worldwide coverage have been hampered by logistical and supply chain issues (5). Furthermore, new strains of the virus continue to emerge, raising concerns about vaccine effectiveness and the possibility of future outbreaks (4).

Despite these obstacles, the need for effective COVID-19 therapies remains critical. Vaccination alone

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cannot address the immediate requirements of infected individuals (3-5), even those with severe symptoms (4,5), nor can it provide a cure for developing virus strains. Although the specific pathophysiological mechanism of COVID-19 is unknown, clinical data suggest that COVID-19-infected individuals frequently experience an increase in cytokine levels, referred to as a "cytokine storm" or "cytokine release syndrome" (6). This aberrant cytokine level is thought to be associated with the significant worsening of health conditions in infected individuals (7). As a result, reducing the increased inflammatory response induced by COVID-19 may be critical in minimizing disease severity and related health consequences (8,9). Endor is a new drug used for its anti-inflammatory properties. Endor, manufactured by Ltd Pty Australia GNP, is an oral capsule (soft gel) and was approved and registered in Australia in 2017 (Registration No: 283065) as therapeutic administration goods (10). This is a natural anti-inflammatory compound consisting of turmeric rhizome, fish oil (containing omega-3), docosahexaenoic acid (DHA), eicosapentaenoic acid (EPA), vitamin C, zinc sulfate, and wheat germ oil, which is used to effectively treat autoimmune diseases such as dermatitis, psoriasis, and multiple sclerosis (11). This study aimed to determine the safety and effectiveness of the ENDOR oral combination drug in the treatment of patients with COVID-19.

## Materials and Methods

### Study design

This study was a double blind randomized controlled trial. The Tehran University of Medical Sciences Institutional Review Board (IR.TUMS.MEDICINE.REC.1400.676) and the Iranian Registry of Clinical Trials (IRCT20100601004076N26) were obtained prior to the initiation of the study. The study was double-blind; the person who collected the clinical data and the participants were blind. Participants who consented to participate in this study were randomized using computer-generated random numbers.

### Participants

All COVID-19 patients who were admitted to the Imam Khomeini hospital complex from April 2022 to April 2023 and who were 18-75-Year-Old signed the consent form to participate in this study, were not pregnant, and did not need mechanical ventilation at admission.

### Procedures

All patients received 200 mg of Remdesivir IV on the first day, followed by 100 mg for 4 days. Other treatments, including medication, were prescribed in accordance with national COVID-19 guidelines. In the Endor group, patients received two tablets every 8 hours for 5 days in addition to all the standard treatments mentioned earlier. The full treatment protocol was registered at https://www.irct.ir/trial/54315.

Endor capsule contains Betacarotene: 2.5 mg, Curcuma longa rhizome extract: equivalent to 1.25 g of dried rhizome and equivalent to2375 mg Curcumin, Fish Oil-Rich in Omega 3 acids: 250 mg, (equivalent to 30 mg docosahexaenoic acid [DHA] and equivalet to 45 mg eicosapentaenoic acid [EPA], equivalent to 75 mg Omega 3 marine triglycerides), Sodium ascorbate: 56.8 mg, (equivalent to 50 mg Ascorbic acid [Vitamin C]), Wheatgerm Oil: 75 mg, Zinc Sulfate: 27.62 mg, (equivalent to 10 mg Zinc). Ghadiminezhad Daru, Tehran, Iran, has manufactured this capsule.

### Outcomes

The outcome of this study includes vital signs, serum electrolytes (sodium, potassium, and calcium), C-reactive protein, white blood cell count, lung involvement, mortality, and COVID-19-PCR. All variable measurements were done on days 1 (start of treatment), 3 (3 days after treatment initiation), and 5 days after treatment initiation.

### Statistical analysis

SPSS V27 is used for statistical analysis. A *P*.05 is considered significant. All continuous variables were compared between the two groups by an independent t-test. Categorical and nominal variables were compared using the Chi-square or Fisher exact test. To examine changes over time, a repeated-measures ANOVA was used. The MANOVA test was used to analyze the relationships among smoking status, treatment group (Endor vs Placebo), and all continuous measured variables.

## Results

In this study of 200 patients (50% in the Endor group and 50% in the placebo group), 60.5% were male, and the mean age was 65.02±14.94 (Table 1). The mortality rate was 1.0 percent (2 patients in the Endor group), and there was no significant difference between the two groups. All COVID-19 PCR results were positive at day 1; at day 3, just 89% (*P*=.066); and at day 5, only 28% (*P*=.096).

Although baseline RR was significantly higher in the

Endor group (*P*=.001), oxygen saturation (*P*=.001) and calcium level (*P*=.031) were significantly lower in the Endor group compared to the placebo group.

According to the repeated-measures ANOVA, there were no statistically significant differences between the Endor and control groups over time for temperature (*P*=.075), WBC (*P*=.095), CRP (*P*=.108), sodium (*P*=.323), or calcium (*P*=.352; Figure 1). The important point here is that the slopes of the decreases in ESR and body temperature, as well as the slope of the increase in oxygen saturation in the Endor group, were higher than those in the control group.

The repeated measures ANOVA revealed (Figures 1 and 2) statistically significant differences between the Endor and control groups across time for the variables of respiratory rate (*P*=.003), oxygen saturation (*P*<.001), and potassium (*P*=.031). The decreasing slope of the respiratory rate in the Endor group was significantly higher than in the control group.

According to the results of MANOVA (Table 2 and Supplement Table 1), patients' smoking status interacts with treatment (Endor vs. Placebo), resulting in changes in CRP on day 1, temperature, O2 saturation, and calcium on day 3, and sodium on day 5. Patients who were smokers had a higher CRP on day 1 compared to non-smokers in both treatment groups. Body temperature (fever) in the Endor group (either smoker or non-smoker) was lower compared to the placebo group. Additionally, O2 saturation in the Endor group (either smoker or non-smoker) was higher compared to the placebo group. Both findings suggest that Endor helps reduce fever and increase O2 saturation in smokers and non-smokers.

**Table 1. Demographic and clinical variables of the study in two groups of patients**

| | | All patients (n=200) | | Endor (n=100) | | Placebo (n=100) | | |
|---|---|---|---|---|---|---|---|---|
| | | **N** | **%** | **N** | **%** | **N** | **%** | ***P*** |
| **Lung involvement** | **0-10** | 90 | 45% | 32 | 32% | 56 | 56% | <.001 |
| | **10-30** | 88 | 44% | 43 | 43% | 44 | 44% | |
| | **30-50** | 22 | 11% | 25 | 25.0% | 0 | 0.0% | |
| | **50-70** | 0 | 0.0% | 0 | 0.0% | 0 | 0.0% | |
| | **More than 70** | 0 | 0.0% | 0 | 0.0% | 0 | 0.0% | |
| **Gender** | **Male** | 121 | 60.5% | 73 | 66.3% | 48 | 53.3% | .064 |
| | **Female** | 79 | 39.5% | 37 | 33.6% | 42 | 46.6% | |
| **Discharge** | | 198 | 99% | 98 | 98% | 100 | 100% | .466 |
| **0utcome** | | | | | | | | |
| **PCR Covid-1** | **Death** | 2 | 1.0% | 2 | 2% | 0 | 0.0% | N/a |
| | **Not Detected** | 0 | 0.0% | 0 | 0.0% | 0 | 0.0% | |
| | **Detected** | 200 | 100.0% | 100 | 100.0% | 100 | 100.0% | |
| **PCR Covid3** | **Not Detected** | 22 | 11% | 24 | 24% | 6 | 6% | .066 |
| | **Detected** | 178 | 89% | 76 | 76% | 94 | 94% | |
| **PCR Covid 5** | **Not Detected** | 144 | 72.0% | 74 | 74% | 78 | 78.0% | .096 |
| | **Detected** | 56 | 28.0% | 36 | 36% | 22 | 22.0% | |
| | | **Mean** | **SD** | **Mean** | **SD** | **Mean** | **SD** | |
| **Age** | | 65.02 | 14.94 | 66.65 | 15.14 | 63.39 | 14.64 | .123 |
| **Respiratory rate (RR) 1** | | 19.43 | 3.14 | 20.17 | 3.26 | 18.70 | 2.84 | .001 |
| **Temperature (T) 1** | | 37.16 | .51 | 37.12 | .46 | 37.21 | .55 | .212 |
| **Oxygen saturation 1** | | 92.05 | 3.14 | 91.32 | 3.48 | 92.79 | 2.57 | .001 |
| **Na 1** | | 136.48 | 4.76 | 136.92 | 5.03 | 136.04 | 4.45 | .192 |
| **K 1** | | 4.06 | .66 | 3.98 | .73 | 4.14 | .58 | .088 |
| **Ca 1** | | 8.49 | .72 | 8.38 | .73 | 8.60 | .71 | .031 |
| **White blood cell (WBC) 1** | | 9.00 | 4.47 | 9.15 | 4.86 | 8.85 | 4.07 | .637 |
| **C-reactive protein (CRP) 1** | | 86.66 | 48.50 | 90.99 | 43.71 | 82.24 | 52.80 | .205 |
| **RR 3** | | 18.72 | 2.73 | 19.06 | 3.06 | 18.37 | 2.32 | .693 |
| **T 3** | | 36.98 | .38 | 36.88 | .40 | 37.09 | .34 | <.001 |
| **Oxygen saturation 3** | | 92.86 | 2.38 | 92.95 | 2.42 | 92.77 | 2.35 | .604 |
| **Na3** | | 144.32 | 90.07 | 151.13 | 127.25 | 137.51 | 4.47 | .286 |
| **K3** | | 4.03 | .42 | 4.03 | .47 | 4.03 | .36 | .987 |
| **Ca3** | | 8.22 | .61 | 8.13 | .68 | 8.30 | .51 | .045 |
| **WBC3** | | 9.69 | 8.10 | 9.78 | 6.84 | 9.59 | 9.25 | .871 |
| **CRP3** | | 65.22 | 38.82 | 64.96 | 35.37 | 65.46 | 42.08 | .929 |
| **RR5** | | 18.66 | 2.57 | 18.79 | 2.84 | 18.54 | 2.26 | .510 |
| **T5** | | 36.88 | .37 | 36.83 | .36 | 36.94 | .37 | .040 |
| **Oxygen saturation 5** | | 93.73 | 1.97 | 93.73 | 2.07 | 93.73 | 1.87 | .984 |
| **Na 5** | | 138.17 | 4.97 | 138.78 | 5.08 | 137.56 | 4.80 | .082 |
| **K 5** | | 4.11 | .41 | 4.14 | .39 | 4.08 | .43 | .246 |
| **Ca 5** | | 8.35 | .69 | 8.23 | .79 | 8.47 | .56 | .013 |
| **WBC 5** | | 8.92 | 4.23 | 9.80 | 5.10 | 8.02 | 2.85 | .003 |
| **CRP 5** | | 37.65 | 28.42 | 36.30 | 29.70 | 39.04 | 27.13 | .498 |

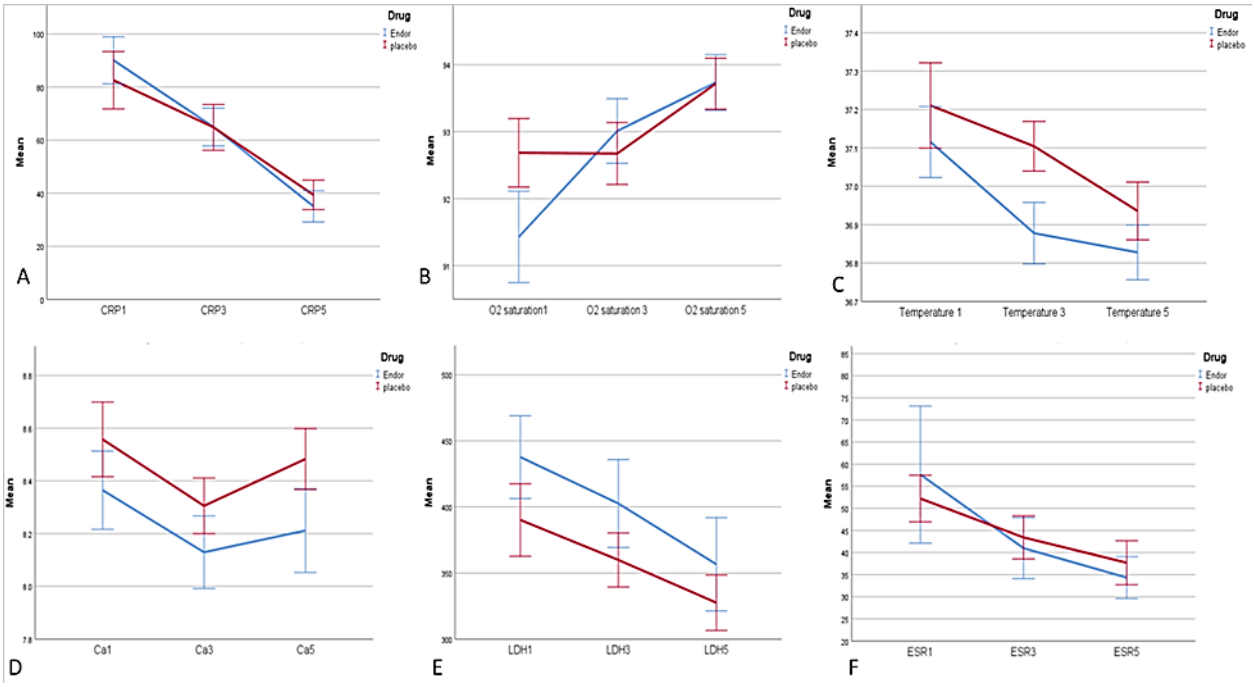


**Figure 1.** Longitudinal change of (A) CRP, (B) O2 saturation, (C) body temperature, (D) calcium, (E) LDH, and (F) ESR between two groups (Blue: Endor, Red: placebo)

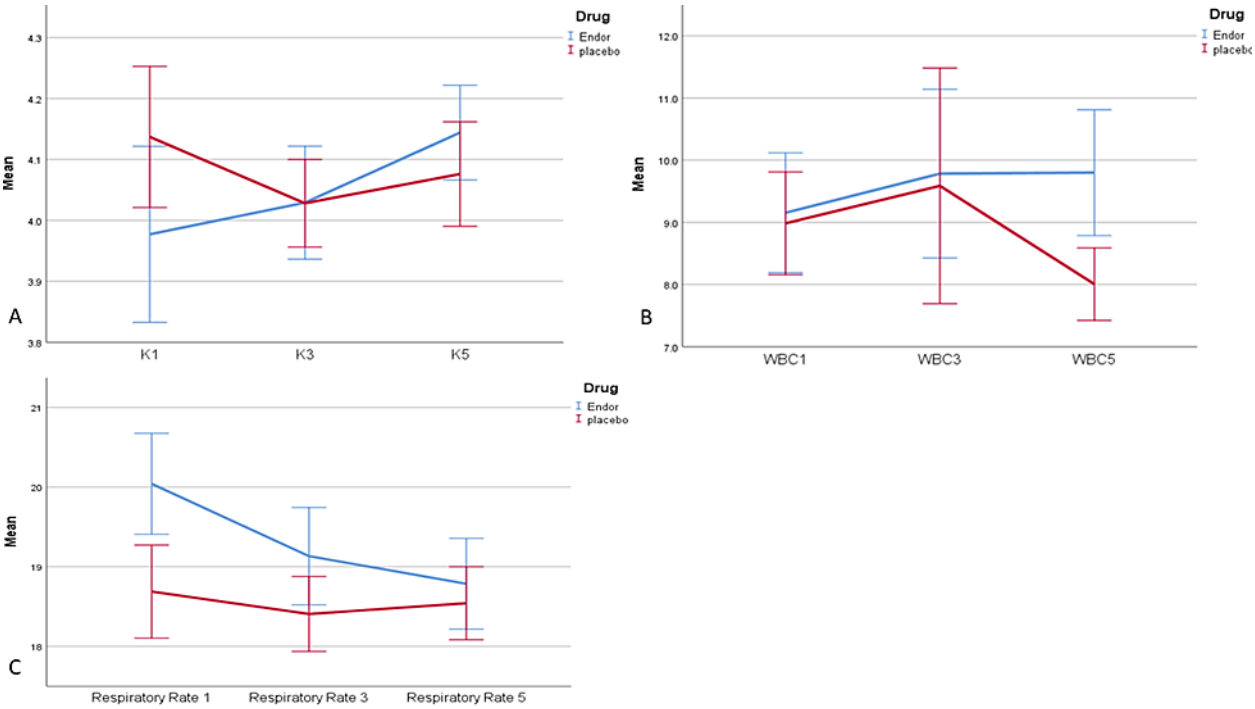


**Figure 2.** Longitudinal change of (A) potassium, (B) WBC, (C) respiratory rate, and between two groups (Blue: Endor, Red: placebo)

**Table 2. Results of MANOVA**

| | Endor | | | | Placebo | | | | *P* |
|---|---|---|---|---|---|---|---|---|---|
| | Smoking Status | | | | Smoking Status | | | | |
| | No | | Yes | | No | | Yes | | |
| | Mean | SD | Mean | SD | Mean | SD | Mean | SD | |
| **RR1** | 20.47 | 3.89 | 20.87 | 2.27 | 19.59 | 2.73 | 19.83 | 2.29 | .333 |
| **T1** | 37.09 | .44 | 37.15 | .45 | 37.37 | .68 | 37.07 | .34 | .118 |
| **Oxygen saturation 1** | 92.11 | 3.01 | 92.22 | 3.44 | 92.31 | 2.41 | 93.00 | 2.13 | .586 |
| **Na1** | 136.61 | 4.48 | 139.06 | 5.03 | 138.03 | 4.52 | 137.17 | 4.24 | .468 |
| **K1** | 3.96 | .75 | 4.12 | .58 | 4.14 | .54 | 3.98 | .21 | .106 |
| **Ca1** | 8.48 | .82 | 8.27 | .74 | 8.66 | .62 | 8.23 | .50 | .396 |
| **WBC1** | 8.63 | 4.48 | 10.71 | 5.02 | 9.23 | 3.94 | 8.56 | 5.00 | .340 |
| **CRP1** | 98.24 | 41.93 | 99.34 | 42.39 | 63.07 | 49.14 | 117.83 | 45.12 | .016 |
| **RR3** | 19.32 | 3.46 | 20.16 | 2.91 | 19.32 | 1.87 | 20.00 | 1.48 | .750 |
| **T3** | 36.83 | .39 | 36.92 | .37 | 37.13 | .30 | 37.10 | .23 | .004 |
| **Oxygen saturation 3** | 93.76 | 2.15 | 93.44 | 2.18 | 92.32 | 2.14 | 92.33 | 2.10 | .008 |
| **Na3** | 172.34 | 206.27 | 140.03 | 5.03 | 138.97 | 3.74 | 137.42 | 5.57 | .584 |
| **K3** | 3.96 | .47 | 4.10 | .42 | 3.99 | .45 | 3.96 | .23 | .431 |
| **Ca3** | 8.20 | .59 | 7.94 | .79 | 8.47 | .46 | 7.93 | .70 | .025 |
| **WBC3** | 8.56 | 3.70 | 11.05 | 7.66 | 10.56 | 11.73 | 8.28 | 4.12 | .380 |
| **CRP3** | 66.72 | 34.35 | 71.69 | 40.25 | 49.48 | 40.12 | 75.17 | 42.27 | .388 |
| **RR5** | 19.32 | 2.53 | 20.22 | 2.59 | 19.18 | 1.96 | 20.67 | 1.83 | .139 |
| **T5** | 36.84 | .43 | 36.88 | .34 | 37.01 | .38 | 37.16 | .28 | .054 |
| **Oxygen saturation 5** | 93.84 | 2.30 | 93.69 | 2.05 | 93.79 | 1.32 | 93.50 | 1.73 | .947 |
| **Na5** | 137.71 | 3.79 | 141.72 | 6.10 | 138.52 | 3.97 | 134.83 | 7.44 | .005 |
| **K5** | 4.12 | .43 | 4.11 | .42 | 4.14 | .43 | 4.01 | .56 | .074 |
| **Ca5** | 8.42 | .76 | 8.08 | .90 | 8.61 | .59 | 8.15 | .52 | .053 |
| **WBC5** | 9.22 | 4.29 | 10.46 | 5.50 | 7.88 | 2.33 | 7.02 | 2.84 | .129 |
| **CRP5** | 42.86 | 27.41 | 39.75 | 35.75 | 32.48 | 26.89 | 49.67 | 36.35 | .466 |

## Discussion

This study aimed to determine the safety and effectiveness of the ENDOR oral combination drug in the treatment of patients with COVID-19. As the most important findings, the results showed that Endor, in combination with other COVID-19 standard treatments, results in faster recovery by improving oxygen saturation, reducing respiratory rate and body temperature (fever), and also a faster reduction in CRP compared to the placebo group. Endor did not show any significant change in PCR results, but it was found that Endor, as an anti-inflammatory drug, may interact with a patient's smoking status. It is well known that smoking is associated with molecular inflammatory responses (12). Kaur *et al*., (13) proposed that detecting susceptible individuals (particularly those with a history of smoking or vaping) and detecting them early, as well as targeting the ACE2 receptor (and isoforms), surface proteases, and other immunological and inflammatory targets, could be a game changer in managing the spread of this pandemic and subsequent infections. Our findings advance the current understanding about the role of drugs with anti-inflammatory features, such as Endor, to target smoker patients. According to our findings, Endor improved O2 saturation in both smoker and non-smoker patients compared with the placebo group, despite smoker patients having higher oxygen saturation on the first day. Interestingly, non-smoker patients in the Endor group had a higher oxygen saturation compared to smokers on day 3. Although body temperature on day 1 was not significantly different between groups, patients in the Endor group had lower body temperature (fever) than those in the placebo group, and, more interestingly, it was even lower in non-smoker patients in the Endor group than in smoker patients.

Endor contains fish oil, omega-3, DHA, EPA, and vitamin C. Some early studies (14,15) on the safety and benefits of omega-3 fatty acids, DHA, and EPA suggested that their anti-inflammatory properties and reduced risk of thrombosis make them promising for the treatment of COVID-19 patients. Our findings support the benefits and efficacy of omega-3, DHA, and EPA as part of the treatment of COVID-19 patients. The most important benefits of omega-3, DHA, and EPA, according to previous studies (14,15), are to prevent hospitalization and faster recovery, which is aligned with our findings. About vitamin C and the benefits of it for COVID-19 patients, the body of current literature (18,19) supports the use of vitamin C along with other COVID-

19 treatments. But it should be noted that vitamin C is not recommended as monotherapy (16-18), and the risk of allergic reactions should be considered. Zinc is also one of the components of Endor, and meta-analysis results indicate that it is associated with a lower risk of COVID-19 mortality (19). Shakoor *et al*., (17) suggested that the immunomodulatory effects of key dietary components, such as vitamins C, D, and E, zinc, selenium, and omega-3 fatty acids, are well known and have advantages in infectious illnesses. Some of these nutrients have also been demonstrated to play a role in COVID-19 regulation. Additionally, Endor contains turmeric rhizome (Curcuma longa rhizome), whose emerging evidence (20,21) suggests promising benefits for treating patients with autoimmune disorders as well as COVID-19. One of the advantages of Endor is that it contains many of the natural anti-inflammatory compounds (key dietary components), such as vitamin C, zinc, omega-3, and so on, which reduces the number of pills patients need to take every day .

This is the first study to determine the safety and efficacy of Endor as part of the COVID-19 treatment. The results are promising, and the efficacy of Endor in outpatient settings should be considered in future studies .

According to this study, ENDOR with anti-inflammatory properties helps COVID-19 hospitalized patients recover faster by improving oxygen saturation, reducing fever, and decreasing respiratory rate. ESR and CRP decreased more rapidly in the ENDOR group than in the placebo group. Endor may interact with patients' smoking status, and it is beneficial for both smokers and non-smokers.

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