ORIGINAL ARTICLE e-ISSN: 2349-0659 p-ISSN; 2350-0964

A Prospective, Open-Label, Randomized-Controlled Study to Evaluate the Efficacy and Safety of Amrta Karuna Syrup in Mildly Symptomatic COVID-19 Patients

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Abstract

Background: Infections and infectious diseases persist as a major cause of mortality and morbidity among humans and a prime challenge for the healthcare sector. This challenge has presented with newer tasks each time and sometimes resulted in pandemic. Estimates indicate that about 60% of infectious diseases and 70% of emerging infections in humans are zoonotic in origin, with two-thirds originating in wildlife. Severe acute respiratory syndrome (SARS) is a respiratory infection caused by a coronavirus. SARS was first reported in 2003, which resulted in an epidemic condition by 2004. Later, with the emergence of SARS-Cov-2 in 2019, it has been evident that viruses are prone to mutation and surface as new variants. Because of vaccine hesitancy, contraindications to take the vaccine, and potential reduced vaccine effectiveness against these variants of concern, drug and antibody prophylaxis serves as an important intervention against COVID-19. **Conclusion:** Prophylaxis is an important approach in handling infectious diseases; with this background, this paper is a presentation of a randomized clinical trial for evidence toward the safety and efficacy of a herbal combination of drugs in the management of mildly symptomatic COVID-19 patients.

Keywords: COVID-19; SARS-CoV-2; Amrta Karuna Syrup; Herbal medicine; Randomized controlled trial; Efficacy; Safety.

Asian Pac. J. Health Sci., (2026); DOI: 10.21276/apjhs.2026.13.3.28

Introduction

Coronavirus or novel coronavirus is also called severe acute respiratory syndrome (SARS)-CoV-2 and named by the World Health Organization (WHO) as COVID-19 which was detected in Wuhan city, Hubei Province, China by the end of 2019 and has caused unprecedented panic across the world.[3] The rapid transmission of this virus from human to human led the World Health Organization (WHO) to declare this as the public health emergency of international concern and called it a global pandemic.[4] Globally, as of July 25, 2022, there have been 566,977,818 confirmed cases of COVID-19, including 6,376,503 deaths, reported to the WHO.[5] As of July 2022, India has reported 4,39,05,621 of COVID-19 cases and 5,26,074 COVID-19 deaths.[6] Considering the fact that COVID-19 requires a structured approach covering preventive care, management in early stages of confirmed disease as well as hospital care for moderately and critically ill patients. It is imperative that the role of the AYUSH sector is harnessed to ensure optimal use of the scarce health care resources available in the country.[7] The WHO has also recommended inclusion of traditional medicine in its COVID-19 strategic preparedness and response plan.[8] An effective immune system must have the ability to interpret changes in the world around it and respond properly. Research is conducted worldwide to develop immunity against COVID-19. Ayurveda is one of the sciences which emphasize on the promotion of health and prevention of diseases rather than the treatment of disease conditions. Adaptation of disease control ideologies for the enhancement of immunological status is ideally possible through Ayurveda. Ayurveda pays larger emphasis on building the strength of mind and body to cope with various stressors, including infection. Similar to innate and acquired immunity, the Ayurveda concept of immunity (*Bala* or strength) is classified as natural (*Sahaja*), chronobiologic (*Kalaja*), and acquired (*Yuktikrut*).[9]

In Ayurveda, several treatment options are available for enhancing immunity against respiratory illnesses; these include certain immune-modulators (known as Rasayana) and local and systemic interventions.[10] Local prophylaxis measures such as herbal decoctions, consumption of hot water, gargling with medicated water, and steam inhalation are described in Ayurveda for respiratory diseases.[11] It is clearly evident that such traditional measures can positively influence mental health and the immune system through modulating psycho-neuroimmune pathways. At present, there are many allopathic drugs under investigation for prophylactic use against COVID-19, and it seems that several prophylactic measures are insufficient. The therapeutic and prophylactic potential of traditional and complementary medicine systems such as Ayurveda and Yoga can be proven effective and adjuvant therapy for COVID-19.[4] Government of India has taken numerous initiatives to make use of the vast potential of Ayurveda

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How to cite this article: Sridhar S, Sridhar S, Hosthota A, Jayanthi CR. A Prospective, Open-Label, Randomized-Controlled Study to Evaluate the Efficacy and Safety of Amrta Karuna Syrup in Mildly Symptomatic COVID-19 Patients. Asian Pac. J. Health Sci., 2026;13(3):140-144.

Source of support: Nil.

Conflicts of interest: None.

Received: 02/06/2026 **Revised:** 17/06/2026 **Accepted:** 23/06/2026

in this pandemic. The Ministry of AYUSH, Government of India, in 2020 implemented a set of guidelines for boosting immunity and measures for self-care based on principles of Ayurveda.[6] However, implementation of Ayurveda for enhancement of immunity would be a positive treatment approach, and this study intends to evaluate the efficacy and safety of an Ayurveda formulation, Amrta Karuna Syrup, in the improvement of immunity in mild symptomatic COVID-19 patients.

Aims and Objectives

The objective of this study is to evaluate the Safety and Efficacy of Amrta Karuna Syrup to Improve Immunity in Mildly Symptomatic COVID- 19 patients.

Materials and Methods

In this open-label prospective study that was conducted at Bangalore Medical College and Research Institute in the month of September 2021, a total of 48 patients were screened, out of which 42 were enrolled based on inclusion criteria. Volunteers who were diagnosed with COVID-19 were enrolled in the study after obtaining Institutional Ethics Committee approval and Informed Consent in writing. Patients diagnosed with COVID-19 and confirmed by reverse transcription-polymerase chain reaction (RT-PCR), with mild symptoms and without complications of upper respiratory infection, were included in the study. The inclusion and exclusion criteria are mentioned in Table 1.

Methodology

Patients were randomly assigned to control and test groups with 21 subjects in each group. The control group subjects received standard of care (SOC), and test group subjects were administered Amrta Karuna syrup orally, 15 mL twice daily along with SOC for a period of 14 days.

Test Drug

The test drug is Amrta Karuna Syrup and it is a poly-herbal formulation which is a potent combination of anti-viral, anti-bacterial, and anti-inflammatory properties along with adaptogen and rejuvenating ingredients. The ingredient of the Amrta Karuna Syrup formula is mentioned in Table 2.

Pre-Clinical Studies

As a part of pre-clinical studies, the test drug was subjected to cytotoxicity and anti-viral studies. The cytotoxicity effect of the composition was determined by *in vitro* cell culture studies. No significant toxicity was observed in all the cells tested which shows a cytoprotective effect. Amrta Karuna was well-tolerated by cells, with half-maximal inhibitory concentrations of >500 μg/mL.

Biological activities of the composition of Amrta Karuna were studied to ascertain its anti-viral activity of virus which includes Dengue, H_1N_1, and H_5N_1. From the experimental results, it is inferred that the composition of Amrta Karuna has maximum anti-viral activity against dengue virus in the range of 0.1 mg/mL, H_1N_1 virus in the range of 0.05 mg/mL, and H_5N_1 virus in the range of 0.5 mg/mL.

Supply and Accountability of Amrta Karuna

Amrta Karuna in syrup dosage form, properly labeled according to the requirements of good manufacturing practice, was supplied by Vopec Pharmaceuticals Pvt. Ltd. The identification, assay testing, dissolution profiles, Package and labeling with cautionary statement, study code, enrolment ID, and manufacture and expiry dates of the Amrta Karuna were prepared by Vopec Pharmaceuticals Pvt. Ltd.

Assessment Criteria

Lactic dehydrogenase (LDH), C-reactive protein (CRP), total leukocyte count (TLC), and D-dimer were monitored for improvement on day 0 and day 14. Renal function test (RFT) and liver function test (LFT) were monitored on day 0 and day 14 for safety assessment. Along with the laboratory parameters, patients were also monitored for vitals, physical examination, and adverse events for safety purposes. Various variables such as RT-PCR, LDH, CRP, TLC, and D-DIMER were recorded. RT-PCR was performed on day 0 and day 10 for patients with mild symptoms. Other variables such as LDH, CRP, TLC, and D-dimer were recorded from baseline (day 0) to the end of the quarantine period, i.e., 14 days. Vital parameters and laboratory safety parameters such as LFT, RFT, Hematology, and Biochemistry parameters were conducted as a part of safety analysis.

Statistical Assessment

All the data recorded were analyzed with range, mean, and standard deviation. T-test is used to determine the statistical significance of the analyzed data.

"T-test" was used separately for within-control group (baseline v/s Visit-3, i.e., day 14) and within test group (baseline v/s Visit-3, i.e., day 14) for safety and efficacy analysis. $P < 0.05$ was considered statistically significant for the study.

Table 1: Inclusion and exclusion criteria

Inclusion criteria	*Exclusion criteria*
• Subjects aged 18–65 years both genders • Patients diagnosed with COVID-19-positive mild symptomatic patients (confirmed by reverse transcription-polymerase chain reaction) - Patients with uncomplicated upper respiratory infection • SpO_2 >94% in room air • Respiratory rate <24/min • No evidence of hypoxemia or breathlessness • Subjects willing to give a written informed consent and come for regular follow-up • Subject willing to abide by and comply with the study protocol.	• Presence of acute hypoxic respiratory failure • Intensive care unit stay • Patients who need mechanical ventilation.

Results

Amrta Karuna Syrup administered orally for a period of 14 days in COVID-19 patients demonstrated significant improvement in clinical symptoms. Patients with fever, cough, and sore throat started responding to the treatment from day 3 [Figure 1], and most of the patients were clinically free of symptoms by day 7. Early recovery from signs and symptoms was observed in most of the patients.

The details of demographic parameters are mentioned in Table 3.

Results on Various Laboratory Parameters

LDH

Mean LDH values in the control group were 246 U/L on day 0 and 311 U/L on day 14. Mean LDH was 256 U/L in the test group on day 0 and 206 U/L on day 14. Mean LDH levels were reduced significantly in the test group compared to the control group and it was statistically significant ($P < 0.0001$). The statistical details of LDH values of both groups are mentioned in Table 4.

CRP

CRP is an important laboratory parameter in assessing the severity of inflammation. In this study, the mean CRP values in the control group were 6.1 mg/L on day 0 and 5.4 mg/L on day 14. The mean CRP of control group was 7 mg/L on day 0 and 2.5 mg/L on day 14. Mean CRP levels were reduced significantly in the test group compared to the control group and it was statistically significant ($P = 0.0236$). The statistical details of LDH values of both groups are mentioned in Table 5.

Table 2: Formulation of Amrta Karuna Syrup (5 mL each)

Ingredients	*Dosage form*	*Dose*
Morinda tinctoria - 200 mg *Azadirachta indica* - 100 mg Aegle marmalades - 100 mg *Tamarindus indica* - 100 mg Total - 500 mg	Syrup	15 mL twice daily after meals

Table 3: Demographics and baseline characteristics

Parameter/Statistics	*Test*	*Control*	*Total*
Number of patients	21	21	42
Mean age (standard deviation)	37.5 (14.16)	37.5 (13.47)	37.5 (13.65)
Sex, *n* (%)			
Female	9 (42.9)	8 (38.1)	17 (40.5)
Male	12 (57.1)	13 (61.9)	25 (59.5)

Subset CRP analysis

CRP response seen in subjects with high CRP values is an important indicator for anti-inflammatory/immunomodulatory activity. In a subset analysis of subjects with CRP more than 10 mg/L, mean CRP was 18.9 mg/L in the test group on day 0 and it decreased to 6.2 mg/L on day 14 which was highly significant.

TLC

Mean TLC is not increased in both the groups during the period of 14 days. The immune response takes several weeks to peak, and hence, this study could not elicit the TLC response. However, it can be concluded that longer duration clinical studies are required to elicit this response.

D-DIMER

Mean D-dimer is showing a decreasing trend in the test group, and in the control group, D-dimer is showing an increasing trend over 14 days of time. Basal mean D-dimer levels were in the normal range at the beginning of study.

RT-PCR viral conversion

The test group showed early RT-PCR negativity as compared to the control group (8.7 v/s 13.6) and it was statistically significant ($P = 0.004$), indicating early viral clearance as represented in Table 6.

Discussion

The study was initiated on August 30th, 2021, and the first subject was enrolled on September 1st, 2021. There were a total of 6 screen failures, and the last subject's last visit was completed on September 30th, 2021. All 42 subjects were distributed equally between the two groups. A detailed physical examination at the screening visit was done. A total of 25 males (59.5%) and 17 females (40.5%) participated in the study. The mean age of participants was 37.5 years.

Safety vitals such as temperature, systolic and diastolic blood pressure, pulse rate, heart rate, and respiratory rate were measured and recorded at all the visits. There was no clinically significant abnormality observed in test and control group subjects, inferring the test drug is safe for administration. Liver function has also been identified as an important predictor for COVID-19 patient mortality.

A recent study suggested that SARS-CoV-2 may directly bind to ACE2-positive cholangiocytes, and therefore, liver abnormalities in COVID-19 patients may be due to cholangiocyte

Table 4: Descriptive statistics for LDH in U/L

Parameter/Day	*Statistics*	*Test*	*Control*	*Total*
LDH (Day 0)	N	21	21	42
LDH (Day 0)	Mean (SD)	256.0 (73.63)	246.1 (95.84)	251.1 (84.56)
LDH (Day 0)	Median	248.0	215.0	233.5
LDH (Day 0)	Min, Max	156, 479	119, 507	119, 507
LDH (Day 14)	N	21	21	42
LDH (Day 14)	Mean (SD)	206.0 (37.24)	311.6 (97.90)	258.8 (90.60)
LDH (Day 14)	Median	194.0	268.0	221.5
LDH (Day 14)	Min, Max	160, 342	212, 550	160, 550

LDH: Lactic dehydrogenase, SD: Standard deviation

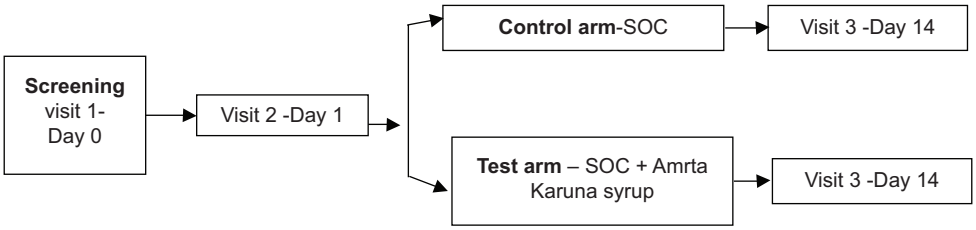

Figure 1: Study activity flow chart. SOC: Standard of care

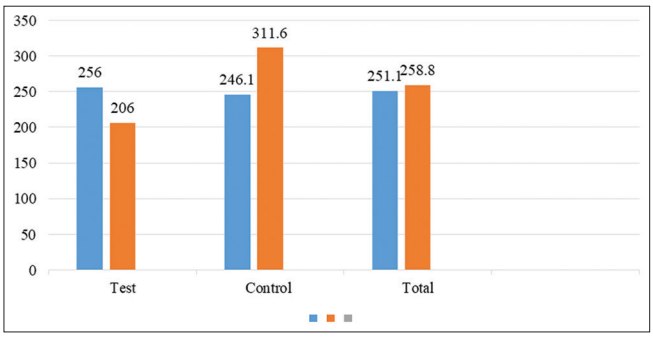

Figure 2: Graphical representation of lactic dehydrogenase in U/L

dysfunction and other causes, such as drug-induced and systemic inflammatory response-induced liver injuries.[11] Regarding the specific and dynamic pattern of liver injury parameters, Lei *et al*., in a wide retrospective multicenter study involving a COVID-19 cohort-derived data set of 5771 patients, reported that AST is strongly associated with mortality risk compared to other parameters, reflecting liver injury.[12] The safety laboratory parameters of RFT and LFT were within normal limits at screening and on day 14. Therefore, it can be concluded that Amrta Karuna syrup formulation is completely safe for human oral consumption.

Amrta Karuna Syrup administered orally for a period of 14 days in COVID-19 patients demonstrated significant improvement in clinical symptoms. Patients with mild symptoms such as fever, cough, and sore throat started responding to the treatment from day 3, and most of the patients were clinically free of symptoms by day 7. Early recovery from signs and symptoms was observed in most of the patients. All the ingredients used in Amrta Karuna Syrup have anti-viral and immunomodulatory action. Various preparations of Azadirachta indica obtained from its different parts have been found to exert anti-bacterial, anti-viral, antimalarial, anti-oxidant, anti-fungal, anti-mutagenic, anti-carcinogenic, contraceptive, and anti-ulcer activity. Marmilide is the most effective viricidal agent interfering with early events of the replicating cycle.[13] These actions aid in early reduction of symptoms and positive pathogenesis.

CRP value on day 0 and day 14 was measured for each group subject. Mean CRP in the test group was significantly lower at day 14 ($P = 0.0236$). Lowering CRP levels significantly helps in reducing the pulmonary inflammation in COVID illness. LDH value on day 0 and day 14 was measured for each group subject. Mean LDH in the test group was significantly lower at day 14 ($P < 0.001$) [Figure 2]. Lowering LDH levels significantly correlates with reduced tissue damage and reduced tissue inflammation which signifies that Amrta Karuna will reduce cytokine storm. TLC levels were reduced in the test group compared to the control group and were not statistically significant ($P = 0.657$). Longer duration studies may be required to elucidate this response. D-dimer did not show an

Table 5: Descriptive statistics for CRP in mg/L

Parameter/Day	*Statistics*	*Test*	*Control*	*Total*
CRP (Day 0)	N	21	21	42
CRP (Day 0)	Mean (SD)	7.0 (8.44)	6.1 (8.07)	6.5 (8.17)
CRP (Day 0)	Median	3.2	2.1	2.5
CRP (Day 0)	Min, Max	0, 26	0, 27	0, 27
CRP (Day 14)	N	21	21	42
CRP (Day 14)	Mean (SD)	2.5 (3.09)	5.4 (5.20)	3.9 (4.46)
CRP (Day 14)	Median	1.0	3.1	2.3
CRP (Day 14)	Min, Max	0, 9	0, 17	0, 17

CRP: C-reactive protein, SD: Standard deviation

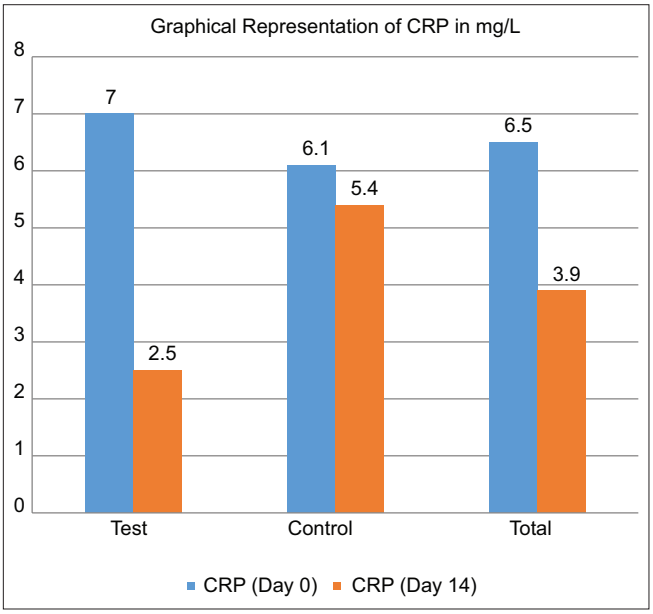

Table 6: RT-PCR viral conversion in days

Groups	*Number of days required for RT-PCR negative (mean with 95% CI*)*
Test group (Amrta Karuna Syrup with standard of care)	8.7 (10.15–9.3)
Control group (standard of care)	3.6 (15.7–10.9)

**P*: 0.004. RT-PCR: Reverse transcription-polymerase chain reaction, CI: Confidence interval

increasing trend in the test group as compared to the control group and was not statistically significant (P = 0.68). Hence, longer studies are required to elucidate this property. In the present study, the test group showed early RT PCR negative as compared to the control group (8.7 v/s 13.6) and it was statistically significant (p value=0.004), indicating early viral clearance.

The preliminary results show that Amrta Karuna Syrup reduced CRP and LDH levels and has also achieved early viral

clearance (early RT-PCR negative) when given along with SOC. However, due to the small sample size in the current study, these findings need to be confirmed in a larger population.

Conclusion

Traditional Systems of Medicine have ample potential and possibilities to be employed for the prevention and treatment options for COVID-19. Certainly, the Ministry of AYUSH has the opportunity to demonstrate the potential of the science in addressing this global health crisis. This paper demonstrates the possibilities of Ayurveda, Siddha, and other traditional systems of Medicine in the management of COVID-19. Studies involving a larger number of patients are needed to further validate Amrta Karuna Syrup. The study outcome shows that Amrta Karuna Syrup shall implement preventive, mitigative, and rehabilitative effects.

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