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Original Research Article

Effect of mulmina mango as an adjunct to standard of care treatment on COVID-19 positive subjects undergoing treatment for COVID-19 in hospital quarantine (Dedicated Covid Health Centre)

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ABSTRACT

Introduction: There are no approved drugs to treat COVID-19, and the vaccine is likely to be ready by early 2021. Many clinical studies are ongoing around the globe to find a cure or prevention of the disease.

Aims: The objective of the proposed study is to determine the efficacy and safety profile of Mulmina Mango as an adjunct to standard of care treatment on COVID-19 positive subjects undergoing treatment for COVID-19 in Hospital Quarantine. Settings and Design: The enrolled subjects were randomized into either of the two treatment arms in the ratio of 1:1. The freshly diagnosed (24-48 hrs.) COVID-19 positive Male or Female is aged 20 to 65 years (both inclusive) hospitalized patients were approached and checked for their eligibility.

Materials and Methods : They were recruited after signing the written informed consent form. The number of patients included in the study is 48.

Statistical Analysis Used: In efficacy, both the treatment arms and the reduction in clinical symptom scale value and ordinal scale value are seen on day 7.

Results: On the ordinal scale, 41.7% of subjects in Treatment arm A showed a reduction of 2 points on the day, and 16.7% of subjects show 2 points reduction in Treatment arm B. In Safety results, there was no clinically significant finding in safety parameters in Treatment arm B.

Conclusions: Mulmina Mango showed encouraging results concerning RTPCR, CRP, Dopamine, IgG, CD4, and CD8 parameters. The properties of Mulmina Mango are highlighted below, along with the parameters for each property.

Key Messages: Mulmina Mango, COVID-19, Treatment Arm A, Treatment Arm B, MoHFW (Ministry of Health and Family Welfare)

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1. Introduction

The outbreak of Novel coronavirus disease (COVID-19) was initially noticed in Wuhan city's seafood market in China's Hubei Province in mid-December 2019.¹ The

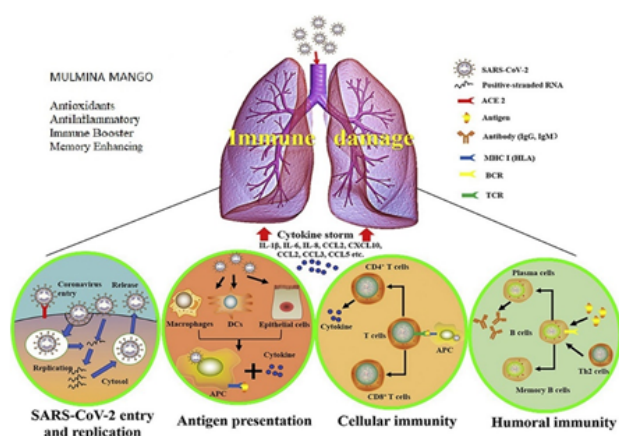
disease has now spread to 214 countries/territories/areas worldwide. WHO (under International Health Regulations) has declared this outbreak as a "Public Health Emergency of International Concern" (PHEIC) on 30th January 2020. On March 11, 2020, WHO declared the novel coronavirus (COVID-19) as a pandemic.² The virus responsible for COVID-19 is a SARS-CoV-2 virus. The symptoms include mild to moderate respiratory illness, presence

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or absence of fever, dry cough, tiredness, aches, sore throat, diarrhoea, headache, loss of taste, loss of smell, and chest pain or pressure range from mild to severe. The severe form presents with pneumonia, severe acute respiratory syndrome, multiple organ failure, and death. The chances of severe illness are high in the elderly and people with underlying medical conditions. The virus spreads through direct contact with the infected person or through droplets of saliva or nasal discharge produced while coughing or sneezing. Infection can also occur if a person touches an infected surface and then touches their eyes, nose, or mouth. When indicated, clinical management includes symptomatic and supportive care, such as supplemental oxygen, mechanical ventilation, and extracorporeal membrane oxygenation (ECMO).³



Coronaviruses (CoVs) primarily cause enzootic infections in birds and mammals but, in the last few decades, have shown to be capable of infecting humans as well. The outbreak of severe acute respiratory syndrome (SARS) in 2003 and, more recently, Middle-East respiratory syndrome (MERS) has demonstrated the lethality of CoVs when they cross the species barrier and infect humans. The most progress has been made on SARS-CoV E, highlighting specific structural requirements for its functions in the CoV life cycle as well as mechanisms behind its pathogenesis. Data shows that E is involved in critical aspects of the viral life cycle and that CoVs lacking E make promising vaccine candidates. The high mortality rate of certain CoVs, along with their ease of transmission, underpins the need for more research into CoV molecular biology, which can aid in the production of effective anti-coronaviral agents for both human CoVs and enzootic CoVs.⁴

Viral and host factors that influence the pathogenesis of SARS-CoV-2. Bats are the reservoir of many coronaviruses, including severe acute respiratory syndrome coronavirus (SARS-CoV) -like viruses. SARS-CoV-2 may originate from bats or unknown intermediate hosts and cross the

species barrier into humans. Virus-host interactions affect viral entry and replication-upper panel: Viral factor. SARS-CoV-2 is an enveloped positive single-stranded RNA (ssRNA) coronavirus. Two-thirds of viral RNA, mainly located in the first open reading frame (ORF 1a/b), encodes 16 non-structure proteins (NSPs). The rest part of the virus genome encodes four essential structural proteins, including spike (S) glycoprotein, small envelope (E) protein, matrix (M) protein, and nucleocapsid (N) protein, and also several accessory proteins. S glycoprotein of SARS-CoV-2 binds to host cell receptors, angiotensin-converting enzyme 2 (ACE2), which is a critical step for virus entry. The possible molecules facilitated membrane invagination for SARS-CoV-2 endocytosis are still unclear. Other virus proteins may contribute to pathogenesis. Host factors (Lower panel) can also influence susceptibility to infection and disease progression. The elderly and people with underlying diseases are susceptible to SARS-CoV-2 and develop into critical conditions.⁵

However, this epidemic highlighted this group of viruses and included them among the causative agents of emerging epidemic diseases. Besides, in 2012, another new CoV responsible for Middle East respiratory syndrome was identified. Both infections were considered a threat to global health security. At present, the third epidemic caused by a CoV is being faced. As of now, there are no approved drugs to treat COVID-19, and the vaccine is ready. Many clinical studies are ongoing around the globe to find a cure or prevention of the disease.⁶

The present study aims to assess the efficacy and safety of an all-natural immunity boosting health drink, Mulmina Mango, as a supplementary therapy in mild to moderate COVID19 positive subjects quarantined or hospitalized Dedicated Covid Health Centre. Mulmina Mango is rich in antioxidants, vitamins, minerals, and mesonutrients. Mulmina Mango contains extracts from mango, Centella Asiatica and Turmeric. The benefits of these are well-known and established for decades.⁷

The Mulmina Mango drink is formulated to cover macro, micro, and meso ingredients in such a way to provide complete nutritional requirements of Antioxidants, Immune booster, and essential vitamins and minerals in a superfruit drink packed in Tetra Pak.

2. Subjects and Methods

2.1. Study objectives

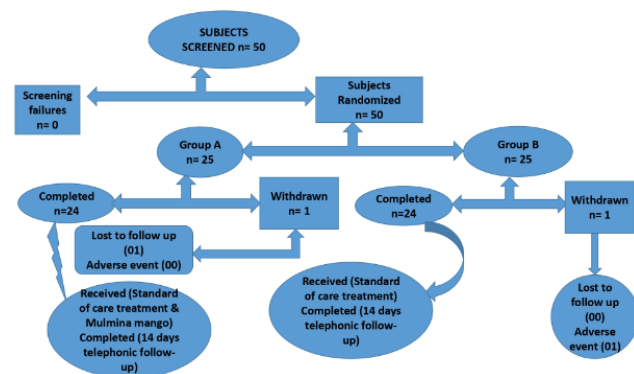
2.1.1. Primary objective

To assess Mulmina Mango efficacy as an adjunct to standard of care treatment on COVID19 positive subjects undergoing treatment in Hospital Quarantine (Dedicated Covid Health Centre). The effectiveness is measured in terms of the following parameters:

1. Faster recovery

Table 1: The statistical results in terms of mean change from baseline to end of treatment in both the treatment arms

Parameter	Mean change in Treatment arm A	Mean change in Treatment arm B
Faster Recovery	Symptom scale: Day 7 (95.8%) Ordinal scale: Day 7	Symptom scale: Day 7 (100%) Ordinal scale: Day 7
Stress level	-39.7	-39.7
Mental Health	-20.6	-20.1
General Well-being/Systemic Health	-11.5	-11.4
Dopamine level	239	89.2
Serotonin level	-11.5	-20.2
IgG antibodies	12.8	-106.6
CD4 T cells	129.8	-75.7
CD8 T cells	142.4	-15.1
Anti-viral property (RT-PCR)	29.2% turned negative	16% turned negative
Ig E	702.3	-432
CRP	-13	1.2

**Fig. 1:** Selection of study population and grouping.

2. Stress level
3. Mental Health
4. General Well-being/Systemic Health
5. Dopamine level
6. Serotonin level
7. IgG antibodies
8. T-Cells (CD4 and CD8 T cells)
9. Anti-viral property (RT-PCR)
10. Ig E and CRP

2.2. Secondary objective

To assess Mulmina Mango's safety as an adjunct to standard of care treatment on COVID-19 positive subjects undergoing treatment in Hospital Quarantine (Dedicated Covid Health Centre). The selection of study population are pictured in Figure 1. The safety is measured in terms of the following parameters:

1. SGOT and SGPT
2. Occurrence of any AE or SAE
3. HRQOL

2.2.1.

2.2.1.1. .

2.2.1.1.1. Selection of study population. The selection of study populations and its grouping as per the target of the study is depicted in Figure 1.

2.3. Inclusion criteria

1. Male or non-pregnant female between 20 to 65 years (both inclusive) of age at the time of enrolment.
2. Subject or LAR providing written informed consent and agrees to follow the study procedure.
3. Women with childbearing potential confirming the use of primary contraception.
4. Mild to moderate freshly confirmed COVID 19 positive report within 24- 48 hours not requiring emergency or ICU care at the time of enrolment and are required to be admitted to the hospital (Dedicated Covid Health Centre) for treatment.

2.4. Exclusion criteria

1. Severe COVID 19 positive subjects requiring ventilation or oxygen support when diagnosed
2. Females who are planning to conceive during the study duration or are pregnant already or are breast feeding.
3. Subjects having serious or unstable respiratory disorders (self-reported).
4. Subject already on immune therapy (self-reported).
5. History of Immunodeficiency or organ transplant (self-reported).
6. Presence of Autoimmune disease (self-reported).
7. Current acute infection or exacerbation of a chronic illness (self-reported).
8. Cancer within the last 5 years (self-reported).
9. Known infection with HIV, Hepatitis B and Hepatitis C (self-reported).
10. Drug abuse/alcohol abuse (self-reported).

11. Patients with severe cardiac pathologies or any chronic illness or comorbid illness (self-reported).
12. Patients on treatment for Diabetes Mellitus.
13. Patients with a history of neurological or psychiatric illness (self-reported).
14. Receiving blood or Immunoglobulins within 3 months (self-reported).

2.5. Removal of patients from therapy or assessment

Patients were free to withdraw from the study at any time without giving a reason. Patients were advised that this would have no negative consequences if they requested to withdraw from the study during the trial. The investigator could also withdraw patients from the trial if they deemed it appropriate for safety or ethical reasons or if it was considered detrimental to the patient's well-being. Complete documentation was made of any withdrawals that occurred during the study in the CRF. The Investigator documented the date and time of the withdrawal and the results of any assessments made at this time. The exit and drop out criteria set was as follows:

1. Volunteer's decision to discontinue the study (protocol dropout).
2. Protocol violation that causes the risk to the research participant and the results of the study.
3. Any medical condition that, at the investigator's discretion, prevents the continuation of the volunteer in the protocol, describing the reason, with its respective proof.
4. An adverse event that prevents the continued use of the product being studied.
5. Disease diagnosis in the course of the study that is part of the exclusion criteria or requiring treatment with medication included in the exclusion criteria.
6. Use of drugs and products not allowed during the study.
7. Not on Investigational product for more than 3 consecutive days

3. Treatments

3.1. Treatments administered

Subjects in Treatment Arm A consumed 2 Tetrapak packs of 200 ml Mulmina Mango each day orally during the treatment duration and SOC treatment prescribed by the treating doctor as per the revised clinical management protocol for COVID-19 as issued by Govt. of India, MoHFW. The treatment duration was defined as the length of hospital stay after recruitment plus 14 days after discharge. Subjects in Treatment Arm B consumed SOC treatment prescribed by the treating doctor as per the revised clinical management protocol for COVID-19 issued by Govt. of India, MoHFW, during the treatment duration. The

treatment duration was defined as the length of hospital stay after recruitment.

3.2. Identity of investigational product

Mulmina Mango was served as a tetrapak pack of 200 ml. Each 200 ml of Mulmina Mango contained 32 gm of Amra (*Mangifera indica*), 40 mg of Mandukaparni (*Centella Asiatica*), 100 mg of Haridra (*Curcuma longa*), Bhavaprakasha and excipients.

3.3. Method of assigning patients to treatment groups

Subjects were randomized in a 1:1 ratio and were allocated to either of the two treatment arms as per the computer's randomization table. The site was provided sealed coded envelopes mentioning treatment arm within each envelope. A unique randomization subject number was printed visibly onto each of the sealed envelopes. The treatment of the randomization subject number was sealed. When a subject was randomized into the trial, the investigator assigned the lowest available randomization subject number at the site before revealing the subject's treatment by scratching off the protective surface of the sealed code. The blank spaces were filled in and signed for on the sealed code before the therapy was uncovered.

3.4. Selection of doses in the study

Mulmina Mango offers 5668 ORAC units per 200 ml tetra Pak which may be fulfil daily requirement of Antioxidants.

3.5. Selection and timing of dose for each patient

The dose is determined as 200 ml of Mulmina Mango twice daily for each COVID-19 positive patient as 200 ml tetra Pak of Mulmina Mango offers 5668 ORAC units which is believed to fulfil daily requirement of Antioxidants.

3.6. Blinding

The study was open-label. Hence, no blinding was required.

3.7. Prior and concomitant therapy

Prior and concomitant therapy was permitted as per the discretion of the Principal Investigator. Principal Investigator had the authority to restrict or allow medication, provided it did not interfere with the treatment procedure and results.

3.8. Treatment compliance

All study treatment was administered by the study investigator or designated member of staff. To ensure drug accountability, the investigator or designated deputy maintained accurate records of the dates and amounts

of drug received, to whom it was dispensed, and accounts of any supplies, which were accidentally or deliberately destroyed; these details were recorded on a drug accountability form.

4. Results

4.1. Efficacy results

The clinical symptom scale and ordinal scale reduction in both the treatment arms are seen on day 7. On the ordinal scale, 41.7% of subjects in Treatment arm A showed a decrease of 2 points on the day, and 16.7% of subjects show 2 points reduction in Treatment arm B. The RTPCR results on day 6 depict a favorable outcome for Treatment arm A. A more significant number of subjects showed negative RTPCR effects in Treatment arm A than treatment arm B. The RTPCR test shows a clinically and statistically significant positive result in Treatment A. There is a macroscale increase in feel-good hormone (Dopamine), antibodies against COVID-19 (IgG antibodies), Immune shaping cells (CD4 T cells and CD8 T cells), and a significant reduction in inflammatory marker (CRP) in Treatment arm A as compared to Treatment arm B. The presence of ORAC Value of 5668 per 200ml pack and statistically significant results in these parameters and clinically acceptable positive change in RTPCR results in Treatment arm A compared to Treatment arm B at the End of treatment shows antioxidant immune-boosting properties of Mulmina Mango. The COVID-19 patients who were given Mulmina Mango and standard of care treatment showed a better recovery rate and better Quality of life than COVID-19 patients who were given standard of care treatment alone. The Table 1 below summarizes the statistical results in mean change from baseline to end of treatment in both the treatment arms.

4.2. Safety results

There was no clinically significant finding in safety parameters in Treatment arm B. However, one AE (Hyperglycaemia) was reported in Treatment arm B. The AE was moderate and was resolved. Since the AE was reported in Treatment arm B, there is no correlation with Mulmina Mango.

5. Discussion

The study's objective is to evaluate the efficacy and safety of Mulmina Mango drink as an adjunct to Standard of care treatment on COVID-19 positive subjects undergoing Treatment in Hospital Quarantine (Dedicated COVID Health Centre). For this study, a total of 50 (fifty) freshly diagnosed (within last 24 -48 hrs) COVID-19 positive adult males and females aged 20 -65 years (both inclusive) undergoing Treatment in Hospital Quarantine (Dedicated

COVID Health Centre) who met the eligibility criteria and agreed to participate in this study by signing the written informed consent were enrolled. All the enrolled subjects were randomized in a ratio of 1:1 in either the Treatment Arm A or Treatment Arm B. Treatment Arm A received Standard of care treatment along with Mulmina Mango, and Treatment Arm B received only Standard of care treatment. The treating doctor prescribed the Standard of care treatment as per the revised clinical management protocol for COVID-19 as issued by the Govt of India, MoHFW. The treatment duration was cumulative of hospital stay length and 14 days post-discharge in the IP group. At the same time, the subjects in the SOC group followed the standard treatment duration. Since the discharge day is discrete for each subject, no particular day was defined for discharge. For the same reason, no treatment duration was specified. The enrolled subjects were provided with Treatment as per the allocated Treatment Arm daily by the authorized research staff. Mulmina Mango drink contains natural ingredients like mango, Centella Asiatica (Mandukaparni), and turmeric. It is formulated to cover macro, micro, and meso ingredients in such a way to provide complete nutritional requirements of Antioxidants, Immune boosters, and essential vitamins and minerals in a superfruit drink packed in Tetra Pak.

The integrated benefit of all these efficient ingredients makes Mulmina Mango the world's first aseptic Tetra Pak-based antioxidant, immune, and stress buster drink which helps boost immunity, overcome common clinical problems of oxidative and mental stress. Mango is also called "King of Fruits," which boasts a magnificent nutritional profile. Mango is rich in dietary antioxidants like Mangiferin, catechins, anthocyanins, quercetin, kaempferol, rhamnetin, benzoic acid many more. Mangiferin is also called a super antioxidant. Mango also contains vitamins (A, B, C, K, and E) and folate, which help boost immunity. Centella Asiatica (commonly known as Mandukaparni) is a well-known traditional medicinal herb used widely for its numerous therapeutic benefits. Centella Asiatica contains triterpenoids (saponins) which are believed to be responsible for their therapeutic effects.

In China, Centella Asiatica is known as Gotu kola and is one of the reported "miracle elixirs of life" known for over 2000 years. It offers antioxidant, anti-inflammatory, memory enhancing, and immune-boosting properties. Turmeric is one of the most effective nutritional supplements in existence. Many high-quality studies have shown numerous health benefits. It contains natural bioactive compounds with powerful medicinal properties. Curcumin is the main active ingredient in turmeric, which has powerful biological anti-inflammatory effects and antioxidants. Curcumin is believed to suppress inflammation and is a potent antioxidant. Besides, curcumin boosts the activity of the body's antioxidant enzymes.

The body requires vitamins and minerals in a minute quantity; however, they play a vital role in the immune system. These are involved in producing cytokines and antibodies, differentiation and proliferation of lymphocytes, and generation of memory cells. These are also important in the continuation and progress of blockade and transform of innate cells, production and activity of antimicrobial proteins, phagocytic activities of neutrophils and macrophages, and balancing the general inflammatory response natural immunity. Malnutrition contributes to poor health and disease outcomes, constantly reducing the body's immune response, increasing susceptibility to infection. The vitamins and minerals that are altered on a body's health are critical, and insufficiency in any of them can lead to severe and even life-threatening conditions. These have many responsibilities, including permitting the body to make enzymes, hormones, and other substances needed for average growth and development. Lack of micronutrients can lead to visible and threatening health conditions, but they can also lead to less clinically significant reductions in energy level, mental clarity, and overall capacity. This can reduce instructional outcomes and work productivity and increase the risk of other diseases and health conditions. Mulmina Mango is rich in antioxidants (ORAC Value of 5668 per 200ml pack), immune-boosting agents, vitamins, and minerals showed a better recovery rate in COVID-19 positive patients when given in addition to Standard of care treatment therapy as compared to Standard of care treatment therapy alone by improving quality of life of COVID-19 positive patients boosting immunity without any side effects. Mulmina Mango showed encouraging results concerning RTPCR, CRP, Dopamine, IgG, CD4, and CD8 parameters. The properties of Mulmina Mango are highlighted below, along with the parameters for each property;

5.1. Recovery rate

A greater number of subjects showed negative RTPCR result in Treatment arm A as compared to Treatment arm B. The RTPCR test showed a clinically and statistically significant positive result in Treatment arm A. On day 6, among 24 subjects in Treatment arm A, 7 subjects (29.2%) turned negative and among 24 subjects in Treatment arm B, 4 subjects (16%) turned negative.

5.2. Feel good hormone

There is a macroscale increase in average Dopamine at day of discharge in Treatment arm A. The average dopamine level increase in Treatment arm A and Treatment arm B is 239 and 89 respectively.

5.3. COVID-19 antibodies

It was observed that there is a macroscale development of IgG antibodies on day of discharge in Treatment arm A (Treatment arm A= 12.8 and Treatment arm B= -106.6).

5.4. Immune boosting property

There is a huge amount of increase in immune shaping cells (CD4 T cells and CD8 T cells). The average CD4 count significantly increased in Treatment arm A and decreased in Treatment arm B (Treatment arm A= 129.8 and Treatment arm B= -75.7).

The average CD8 count significantly increased in Treatment arm A and decreased in Treatment arm B (Treatment arm A=142.4 and Treatment arm B=-15.1).

5.5. Anti-inflammatory effect

There is a significant decrease in inflammatory marker C-Reactive Protein in Treatment arm A at the day of discharge (average change in Treatment arm A= -13 and Treatment arm B= 1.2).

5.6. Anti-allergic activity

There is an average increase of IgE value in Treatment arm A and decrease in Treatment arm B from visit 1 to discharge.

5.7. Antioxidant property

Mulmina Mango contains ORAC Value of 5668 per 200ml pack.

6. Conclusions

Mulmina Mango drink contains natural ingredients like mango, Centella Asiatica (Mandukaparni), and turmeric. It is formulated to cover macro, micro, and meso ingredients in such a way to provide complete nutritional requirements of Antioxidants, Immune boosters, and essential vitamins and minerals in a superfruit drink packed in Tetra Pak. Mulmina Mango showed encouraging results concerning RTPCR, CRP, Dopamine, IgG, CD4, and CD8 parameters. The COVID-19 patients who were given Mulmina Mango along with the standard of care treatment showed a better recovery rate and better Quality of life as compared to COVID-19 patients who were given standard of care treatment alone.

7. List of abbreviations

1. CD4: Cluster of differentiation 4
2. CD8: Cluster of differentiation 8
3. CRP: C-reactive protein
4. HRQOL: Health-related quality of life
5. MoHFW: Ministry of Health and Family Welfare
6. NSPs: Non-structure proteins

7. RTPCR: Reverse transcription polymerase chain reaction
8. SAE: Serious adverse event
9. SARS-CoV: Severe acute respiratory syndrome coronavirus
10. SGOT: Serum glutamic oxaloacetic transaminase
11. SGPT: Serum glutamic pyruvic transaminase

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None.

9. Conflict of interest

None.


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