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### Research Article

## Evaluation of the Safety and Efficacy of T-AYU-HM Premium and Onion Steam Inhalation in Mild to Moderate COVID-19 Patients

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### ABSTRACT

Coronavirus disease (COVID-19) has impacted many nations' health care and their economic growth within no time. This Pandemic situation demands a safe and cost-effective treatment as early as possible to prevent any further suffering. To clinically evaluate the safety and efficacy of T-AYU-HM Premium Tablets (600 mg) and onion steam inhalation in mild to moderate COVID-19 patients. The trial is an open-label, Single-arm study conducted in mild to moderate level coronavirus patients. 30 participants infected by the coronavirus enrolled for the study, on providing informed consent. AYUSH standard mark anti-sickling tablet T-AYU-HM Premium 600mg twice a day and onion steam inhalation once every morning once for 21 days was prescribed to the patients along with strict home quarantine instructions. Both clinical and pathological changes recorded on the baseline, 5<sup>th</sup>, and 21<sup>st</sup> day of the trial. Any adverse events reported by the patients and those observed by the principal investigator recorded. All the patients recovered clinically, and no untoward effects observed during this trial period. A significant reduction ( $p < 0.05$ ) observed in the pathological parameters like C-reactive protein (CRP), erythrocyte sedimentation rate (ESR), and lactate dehydrogenase (LDH). The oxygen saturation ( $SpO_2$ ) level sustained within normal limits during the treatment period suggesting that further complications and hospitalization evaded. The impact of the treatment regimen T-AYU-HM Premium and onion steam inhalation on clinical and pathological parameters suggest that it is safe and indicate its potential candidacy in the treatment of COVID-19.

### INTRODUCTION

2020 is a year that remains challenging and unforgettable to every scientist because of the global outbreak of coronavirus in December 2019. The coronavirus is a member of the coronaviridae family, the largest single-stranded RNA virus capable of infecting and damaging the respiratory system in humans.<sup>[1]</sup> At this moment, the coronavirus has impacted so severely that COVID-19 needs no more introductions because major research articles are available on its pathogenesis and clinical features. In the present day, many countries enforced lockdown again for safety measures. The healthcare warriors are fighting tremendously to save lives till a complete cure is

available. Currently, available treatment options are for symptomatic management only.<sup>[2-4]</sup> Many national and international healthcare agencies are now considering that the alternative system of medicine might have a potential role in the treatment of COVID-19.<sup>[5]</sup>

### T-AYU-HM Premium and Onion Steam Inhalation

Onion is one of the most used vegetables in our routine life, frequently served as a salad. Previous studies and ancient usage suggest that onions do possess antiviral and anti-inflammatory activity. Its usefulness in diabetes and hypertensive patients might be considered important for its potential in the treatment of coronavirus.<sup>[6-10]</sup> Nasya karma is an ancient method and a preferred route of

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administration for steam inhalation in respiratory illness. [11] Therefore, onion steam inhalation is considered a powerful approach to fight against coronavirus. T-AYU-HM Premium 300 mg tablet is a herbo-mineral formulation with anti-sickling activity. The formulation of each tablet of 300 mg consists of vital herbs like *Terminelia chebula* (25 mg), *Tinospora cordifolia* (37.5 mg), *Zingiber officinalis* (25 mg), *Asparagus racemosus* (25 mg), *Piper longum* (37.5), *Punica granatum* (12.5 mg), *Leptadina reticulata* (37.5 mg), *Myristica fragrans* (25 mg), and minerals like the calyx of mica (25 mg), calyx of iron (12.5 mg). [12]

### Why T-AYU-HM Premium Tablets in Coronavirus Patients?

Coronavirus, through its entry site known as angiotensin-converting enzyme (ACE-2) infects and damages the alveoli in the lungs, creating an imbalance in the gas exchange process. This imbalance causes reduced oxygen saturation and leads to an increase in the workload on the heart to maintain the demand. The formulation T-AYU-HM Premium possesses the ability to maintain cellular integrity due to its anti-sickling potential. This concept of preventing cellular integrity might become helpful in preventing red blood corpuscles from lysis due to hypoxia, acidosis, and dehydration. This mechanism can be observed by estimating the level of erythrocyte sedimentation rate. Preventing lysis of red blood corpuscles also improves the coagulation state of the vascular system by retrieving it from hypercoagulation state to normal state observed by estimating D-Dimer level. [13,14] T-AYU-HM Premium prevents cell lysis, and the antioxidants properties of herbs incorporated in formulation might restrict inflammatory mediators' mediated progression in the disease. Therefore, under the alternative system of medicine, T-AYU-HM Premium made from herbo-mineral ingredients claims to be a potential candidate for the treatment of coronavirus infection. A result of the case study, performed after obtaining prior informed consent and undertaking all safety standards, has encouraged the systematic clinical evaluation of T-AYU-HM Premium 600 mg twice daily and onion steam inhalation for 2 mins once a day in coronavirus patients. [15] The study was performed in accordance with prior approval from the Ethics committee.

### Design and Intervention

The trial was as per the following protocol guideline, the declaration of Helsinki, standards of ICH-GCP, and local regulatory guidelines. The study registered prospectively with CTRI and registration number - CTRI/2020/08/027477.

### Aim of the Study

The study aims to clinically evaluate the safety and efficacy of T-AYU-HM Premium and onion steam inhalation in mild to moderate patients of COVID-19.

### Objectives of the Study

The primary objective was to evaluate the total number of participants for improvement in clinical symptoms – fever, Cough, Fatigue, Shortness of breath, Expectoration, Myalgia, Rhinorrhea, Sore throat, Diarrhea, Loss of smell (anosmia), Loss of taste (ageusia) and the total number of participants with a resolution of clinical symptoms fever, Cough, Fatigue, Shortness of breath, Expectoration, Myalgia, Rhinorrhea, Sore throat, Diarrhea, Loss of smell (anosmia), Loss of taste (ageusia).

The secondary objectives were to observe oxygen requirement in participants, improvement in oxygen saturation (SpO<sub>2</sub>), improvement in respiratory rate, improvement in hematological parameters, and improvement in the level of inflammatory markers like c-reactive protein (CRP), erythrocyte sedimentation rate (ESR), and lactate dehydrogenase (LDH) in participants.

### Study Site

The study was conducted at Dhanvantari Clinic, Ayurveda health care and research center, Shreeji Desai market, Vyara-394650, Gujarat. India

### Study Type and Design

The type of the trial was interventional and the design was a single-arm study. Sample size was kept at 30 considering chances of dropouts' rate of 25%, compliance factors, and monetary restrictions. Thirty participants with clinically established coronavirus, confirmed through Rapid antigen test or RT-PCR. Prior informed consents have been received from the participants.

### Inclusion Criteria

- Age 18–80 years
- Both male and female
- Mild to Moderate cases under home quarantine
  - Mild patients are those with SpO<sub>2</sub> > 94% on room air, Respiratory rate < 24 per minute, and HRCT if required shows < 25% lung involvement.
  - Moderate patients are those with SpO<sub>2</sub> between 90–94% on room air, Respiratory rate > 24 per minute, and HRCT if required shows 25–50% lung involvement.
- Able to perform onion steam inhalation once a day
- Patients can consume oral formulations
- Able to provide informed consent

### Exclusion Criteria

- Require mechanical ventilation
- Unable to perform onion steam inhalation once a day
- Have a serious end-stage illness
- Pregnant/lactating women
- Children below 18 years of age

### Interventions

In the current study, participants advised to take Tablet T-AYU-HM Premium 600 mg twice a day orally and onion



steam inhalation for 2 mins once a day for 21 days under strict home quarantine guidelines. For onion steam inhalation, wash your face gently before therapy. Add 15 gm finely chopped onion in 250 mL boiling water and inhale the steam for a maximum of 2 mins only once a day.

### Duration and Monitoring of Trial

During the trial period of 21 days, various clinical and pathological markers recorded on the baseline, 5<sup>th</sup> day and 21<sup>st</sup> day of the study. All the adverse events were recorded, reported by the patients or observed by the principal investigator. Epidemiological studies indicated that the median duration between contacting a sick/carrying individual and exhibiting clinical symptoms of COVID-19 infection is five days and that the median duration of hospitalization in people that do not survive the virus is 14 days.<sup>[16]</sup> For adhering to treatment for 21 days instead of 14 days, we can also avoid probable transmission from convalescent.

### Data Collection and Analysis

All the data like the informed consent, case report form, and patients' vitals, clinical and pathological data were well maintained. The data analyzed by standard statistical software SPSS v.20. The demographic and baseline characteristics were summarized using Descriptive statistics. Categorical variables summarized by frequency distribution for each categorical component (relative frequencies and percentage). Results reported as mean  $\pm$  standard deviation for continuous variables and repeated paired data evaluated using one-way repeated measure analysis of variance test. Results considered significant at  $p < 0.05$ .<sup>[17]</sup>

## RESULTS AND DISCUSSION

The objective to consider a single-arm trial was to obtain preliminary efficacy of the treatment and the collection of safety aspects. Despite several limitations, a single-arm study considered when placebo control is ethically not desirable, and options for controlled trials are limited.<sup>[18]</sup> In this study, there were 30 participants amongst them 50% were male and 50% were female. The mean age of participant was  $45.50 \pm 15.78$  (mean  $\pm$  Standard deviation). Based on inclusion criteria there were 53.33% mild and 46.66% moderate patients having coronavirus infection

### Effect on Clinical Parameters in Participants

All the patients showed remarkable improvement in the clinical parameters and recovered at the end of the trial. A positive point during the trial was that none of the participants develops any complications. The effect of the investigational product on clinical parameters depicted in Table 1 indicate that symptoms like fever, fatigue, cough, and shortness of breathing showed exceptional improvement on the 5th day in participants. The treatment

can sustain oxygen levels to promote restoration of clinical parameters like shortness of breath and fatigue. As the symptoms subside gradually, patients' quality of life might improve. This improvement in symptoms might enhance the psychological status and prevents anxiety-based complications in participants. Onion steam inhalation creates a warm environment in the nasal passage that might reduce the penetration of the virus.

Clinical parameters like anosmia (loss of smell sensation) and ageusia (loss of taste sensation) observed on baseline days progressively recovered at the end of the trial period. The change in body weight of the participants on baseline day (0 days)  $69.75 \pm 13.47$ , 5th day  $69.62 \pm 13.45$  and on 21<sup>st</sup> day  $69.83 \pm 13.53$  suggests there was no marked weight loss in the participants.

Preventing the progress of infection in patients from mild to moderate and moderate to severe is a significant concern in the treatment of COVID-19. Oxygen saturation is an important marker to recognize the progression of disease symptoms to complications in coronavirus infection. Hypoxia-induced complications advance rapidly and damage the organ, which is considered accountable for mortality and slow post-COVID-19 recovery in patients. Oxygen requirement continued to be above the designated level (94% SpO<sub>2</sub>) suggest that there was no burden on the cardiovascular system. It might be vital to acknowledge this, as complications in coronavirus infected patients are usually associated with hypoxia. The results of SpO<sub>2</sub> mentioned in Table 2 suggest that oxygen saturation remains balanced and that there wasn't a decline in the level. On the other hand, the respiratory rate has shown a statistically significant improvement.

Patients with mild and moderate symptoms have a good prognosis but might lead to severe complications including, death in COVID-19. The extent of damage in the lung caused by coronavirus might vary in each patient, but laboratory markers like ESR, CRP help understand the severity of the inflammatory destruction generated by the virus. Therefore inflammatory markers are

**Table 1:** Effect on primary endpoint/ clinical parameters

| Variables, n (%)    | Baseline (0 days) | 5 <sup>th</sup> day | 21 <sup>st</sup> day |
|---------------------|-------------------|---------------------|----------------------|
| Fever               | 17 (56.67)        | 01 (03.33)          | 01 (03.33)           |
| Coughing            | 14 (46.67)        | 03 (10.00)          | 01 (03.33)           |
| Fatigue             | 23 (76.67)        | 03 (10.00)          | 03 (10.00)           |
| Shortness of Breath | 13 (43.33)        | 04 (13.33)          | 00 (00.00)           |
| Expectoration       | 03 (10.00)        | 00 (00.00)          | 00 (00.00)           |
| Myalgia             | 04 (13.33)        | 00 (00.00)          | 00 (00.00)           |
| Rhinorrhea          | 04 (13.33)        | 00 (00.00)          | 00 (00.00)           |
| Sore throat         | 08 (26.67)        | 04 (13.33)          | 00 (00.00)           |
| Diarrhea            | 01 (03.33)        | 00 (00.00)          | 00 (00.00)           |
| Anosmia             | 14 (46.67)        | 02 (06.67)          | 00 (00.00)           |
| Ageusia             | 11 (36.67)        | 00 (00.00)          | 00 (00.00)           |

**Table 2:** Effect on SpO<sub>2</sub>, Respiratory rate, and pulse rate

| Parameter        | Baseline (0 day) | 5 <sup>th</sup> day | 21 <sup>st</sup> day | p-value |
|------------------|------------------|---------------------|----------------------|---------|
| SpO <sub>2</sub> | 97.63 ± 1.50     | 97.93 ± 1.62        | 97.83 ± 1.23         | 0.683   |
| PR               | 98.37 ± 16.24    | 94.03 ± 14.68       | 92.50 ± 13.75        | 0.068   |
| Respiratory rate | 31.90 ± 9.2      | 27.37 ± 4.87        | 24.67 ± 2.67         | <0.0001 |

Values are presented in Mean ± SD and p-values are estimated by using the One-Way Repeated Measure Analysis of Variance test.

**Table 3:** Effect on inflammatory markers

| Parameter  | Baseline (0 day) | 5 <sup>th</sup> day | 21 <sup>st</sup> day | p-value |
|------------|------------------|---------------------|----------------------|---------|
| ESR(mm/hr) | 37.07 ± 18.83    | 36.53 ± 19.77       | 25.13 ± 17.33        | <0.0001 |
| CRP(mg/l)  | 12.07 ± 10.40    | 6.10 ± 7.77         | 3.69 ± 4.04          | 0.0069  |
| LDH        | 279.70 ± 103.18  | 260.13 ± 167.75     | 174.14 ± 36.85       | 0.0005  |

Values are presented in Mean ± SD and p-values are estimated by using the one-way repeated measure analysis of variance test.

**Table 4:** Effect on hematological parameters

| Parameter         | Baseline (0 days)    | 5 <sup>th</sup> day  | 21 <sup>st</sup> day | p-value |
|-------------------|----------------------|----------------------|----------------------|---------|
| Hb (gm/dL)        | 13.71 ± 1.31         | 13.57 ± 1.41         | 13.19 ± 1.22         | 0.0008  |
| RBC (in millions) | 4.44 ± 0.64          | 4.38 ± 0.61          | 4.26 ± 0.56          | 0.0142  |
| WBC (mcL)         | 5710.00 ± 2512.09    | 6812.67 ± 2819.34    | 10063.33 ± 16987.00  | 0.2211  |
| Platelet (mcL)    | 237866.67 ± 80920.88 | 286300.00 ± 68272.35 | 283133.33 ± 62817.05 | 0.0012  |
| MCHC              | 33.64 ± 1.83         | 33.97 ± 0.86         | 33.89 ± 0.93         | 0.4904  |
| MCH               | 31.31 ± 3.97         | 31.07 ± 3.65         | 31.32 ± 3.67         | 0.5678  |
| MCV               | 92.39 ± 9.97         | 91.38 ± 9.16         | 88.92 ± 17.63        | 0.3535  |
| PCV               | 40.19 ± 3.87         | 39.93 ± 3.76         | 38.78 ± 3.26         | 0.0048  |
| Neutrophils       | 66.63 ± 10.20        | 65.23 ± 9.79         | 64.43 ± 7.93         | 0.6212  |
| Eosinophils       | 3.00 ± 1.11          | 3.97 ± 1.33          | 4.27 ± 1.11          | 0.0006  |
| Lymphocytes       | 30.07 ± 9.33         | 30.03 ± 9.09         | 31.20 ± 7.53         | 0.8175  |
| Monocytes         | 0.43 ± 1.38          | 0.70 ± 1.82          | 0.77 ± 4.01          | 0.8795  |

considered essential to determine the progression of the disease in coronavirus patients.<sup>[19]</sup> Effect of T-AYU-HM premium and onion steam inhalation on C-reactive protein mentioned in Table 3 shows a significant improvement indicating its potential anti-inflammatory activity in the participants. Previous research studies suggest the critical role of inflammation in the progression of the disease and intimating cardiovascular complications.<sup>[20,21]</sup> Erythrocyte sedimentation rate is an imperative inflammatory marker in the assessment of thrombotic complications in patients of COVID-19. The effect on ESR level showed a significant reduction due to the possible role of T-AYU-HM Premium on red blood corpuscle as it maintains cell membrane integrity and prevents lysis. Clinical markers like LDH considers vital in estimating progression in pneumonia and indicate the severity of lung damage.<sup>[22-24]</sup> The effect on LDH showed a significant reduction in participants.

The results of the effect of T-AYU-HM Premium and Onion steam inhalation on other hematological parameters mentioned in Table 4

Improvement in ESR might be because erythrocytes, hemoglobin, and oxygen saturation level sustained. It

could inhibit plasma proteins released due to infection, inflammatory conditions to induce rouleaux formation.<sup>[25]</sup> The ability of the formulation to prevent red blood corpuscle lysis and its effect on the significant reduction in inflammatory markers recommend its potential in reducing the D-Dimer level. D-dimer is also responsible for promoting neutrophil and monocyte recruitment in inflammation.<sup>[26]</sup> Lymphopenia is also a notable marker for patients advancing towards coronavirus.<sup>[27]</sup> Results of lymphocytes in the study indicate observational improvement in participants, which might be a positive treatment outcome. The impact of T-AYU-HM Premium and onion steam inhalation on lymphocyte count demands further studies to establish its significance in the treatment.

## CONCLUSION

T-AYU-HM Premium and onion steam inhalation during the observation period did not produce any untoward effect in the participants. The clinical improvement was remarkable oxygen saturation remains well maintained, not a single participant developed any further complication or required hospitalization. The impact of T-AYU-HM



Premium and onion steam inhalation on the clinical and pathological parameters indicate that it is safe and exhibits efficacy in patients infected by the coronavirus.

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