Research Article

AN OPEN LABEL, MULTICENTRE, MULTI-DOSE, SINGLE ARM TREATMENT CLINICAL TRIAL TO DETERMINE THE SAFETY AND EFFICACY OF NEW NATURAL HEALTH DRINK OF EARTH TEA IN HUMAN ADULT, PATIENTS WITH MILD COVID-19.

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Abstracts:

Background/Objective: Coronavirus disease 2019 (COVID-19) is a viral respiratory illness that inflames the mucous membrane. Alveolar injury and eventually pneumonia result from this. It is brought on by the positive-sense single-stranded RNA virus SARS-CoV-2, also referred to as the novel coronavirus. The signs and symptoms of COVID-19 include fever, dry cough, exhaustion, sore throat, diarrhoea, headache, conjunctivitis, nasal congestion, body aches and pains, fatigue, loss of taste and smell, a skin rash, and discoloration of the fingers or toes. The main focus of research has been on current antiviral medications as prospective COVID-19 treatments. Hence, the present work was focused for clinical studies for the determinations of SARS-COV-2 (COVID-19) safety and efficacy of the new natural health drink of “Earth Tea”. The product of “Earth Tea” Manufactured By Martin Sinclair B4B Corp,40, Remsen Ave, Brooklyn, NY 11212 ,United States.

Methods: An Open Label, Multicenter, Multi-Dose, Single Arm Treatment Clinical Trial in Human Adult Patients with Mild COVID-19 was the main goal of the study. To assess the safety and effectiveness of "Earth Tea" for COVID-19 as well as the safety and tolerability of a multi-dose given to human adult patients with COVID-19 infections.

Results: In the analysis, patients showed a significant reduction in clinical cure and micro biologically cure analysis on Day 02 of evaluation visit. Moreover, significant reduction in the RT-PCR report noted on Day-02 and there were no adverse events reported during course of the study. Therefore, there were no Serious adverse events or deaths reported in this study.

Conclusion: Based on these results obtained in the study, the product is an Earth Tea was found to have a significant efficacy and also a safe product.

Key Words: Earth tea, COVID-19, SARS-COV-2, Clinical trial, Safety and efficacy and Multicenter-Multi-Dose-Single Arm-Treatment Clinical Trial.

Introductions:

Coronavirus disease 2019 (COVID-19) is a viral respiratory illness that inflames the mucous membrane. Alveolar injury and eventually pneumonia result from this. It is brought on by the positive-sense single-stranded RNA virus SARS-CoV-2, also referred to as the novel coronavirus[1]. In the past, coronaviruses were linked to the Middle East respiratory syndrome (MERS) and the severe acute respiratory syndrome (SARS) (MERS) [2]. The signs and symptoms of COVID-19 include fever, dry cough, exhaustion, sore throat, diarrhoea, headache, conjunctivitis, nasal congestion, body aches and pains, fatigue, loss of taste and smell, a skin rash, and discoloration of the fingers or toes [3]. The main focus of research has been on current antiviral medications as prospective COVID-19 treatments. such as Ritonavir, Favipiravir, Lopinavir, and Remdesivir. Some antimalarial medications, including chloroquine and hydroxychloroquine, are utilised in the treatment of COVID-19. Another broad-spectrum antiviral medication used to treat the coronavirus condition is ribavirin. Ivermectin is being investigated as a COVID-19 therapy. Nutrition is important for health, especially when the immune system may need to defend itself. Consuming fresh fruits and vegetables aids in disease prevention and immune maintenance [4].

Hence, the present work was focused for clinical studies for the determinations of SARS-COV-2 (COVID-19) safety and efficacy of the new health drink of "Earth Tea". The product of "Earth Tea" Manufactured by Martin Sinclair B4B Corp,40, Remsen Ave, Brooklyn, NY 11212, United States. Earth Tea is made of a combination of natural vegetable, Aloe Vera and Honey known to help to boosts our immune system. Earth Tea is 1-4 servings per bottle 16oz total with recommended servings of 8oz each, but 4oz can also be used. Earth Tea Extra Strength may be used to continuously boost our immune system, which may be used as 1 bottle every two weeks or at least one bottle per month to assist the immune system. Earth Tea might help with other issues where more than one bottle might be required per month in that case, 2 bottles max within 48 hours can be consumed with 8oz per serving every 8-10 hours. Earth Tea is all natural and might be hard to swallow because of the taste, it may be combined with juice and it will still be effective. Which mainly focused to increase the immunity level in human and helps to maintain the antioxidant levels which help to reduce the symptoms of COVID-19 infection. It is also helps in restoration of smell and taste.

Hence. An Open Label, Multicenter, Multi-Dose, Single Arm Treatment Clinical Trial in Human Adult Patients with Mild COVID-19 [5] was the main goal of the study. To assess the

safety and effectiveness of "Earth Tea" for COVID-19 as well as the safety and tolerability of a multi-dose given to human adult patients with COVID-19 infections.

Materials and Methods:

The study protocol with the number EART-001-21 was created on May 1 and received IEC clearance on July 5 of that same year. 20 Mild COVID- 19 patients in all were screened and participated in the trial. Prior to drug administration and up until the day of visit completion, enrolled participants were present in the clinical institution. The product being studied is called "Earth Tea," and it is made by Martin Sinclair B4B Corp. The 08 ounces of cold tea were taken orally in the morning, and 08 ounces of hot tea were taken orally exactly 12 hours later, two hours before bed. A study was focused for An Open Label, Multicenter, Multi-Dose, Single Arm Treatment Clinical Trial in Human Adult Patients with Mild COVID-19, to assess the safety and effectiveness of "Earth Tea" for COVID-19 as well as the safety and tolerability of a multi-dose given to human adult patients with COVID-19 infections.

The study was conducted as per the pertinent requirements of the Ethical guidelines for biomedical research on human participants, ICMR (2017), ICH (Step 5)[6] 'Guidance on Good Clinical Practice' [7], 'Good Laboratory Practice' [8-9], 'Good Clinical Practices for Clinical Research in India' Guidelines, Good Clinical Laboratory Practice (GCLP) [10], Declaration of Helsinki (Fortaleza, October 2013), New Drugs and Clinical Trials Rules 2019 G.S.R. 227(E) dated 19 Mar 2019 and applicable regulatory requirements.

Diagnosis and main criteria for inclusion: are the patients meet with all following criteria has considered for enrollment in the study: 1.Voluntarily participating in the clinical study; fully understanding and being fully informed of the study and having signed the Informed Consent Form (ICF); willingness and capability to complete all the study procedures. 2.Human adult patient with in the age limit of 18-75 years (both inclusive) were enrolled. 3.Patients who have evidence of laboratory confirmed infection with SARS-CoV-2 by positive RT-PCR were enrolled for this study (within 48 hours prior to randomization) [11-12]. 4.Patients who have uncomplicated respiratory tract viral infection were enrolled in this study. 5. Who have the evidence of controlled diabetic patients with HbA1C limit< 7.0 were enrolled in this study 6. Hypertension Patients up till Hypertension Stage 2 were included in the study (Systolic blood pressure at least 140mm Hg and Diastolic blood pressure at least 90 mm Hg) 7. The patients who have a time interval between symptoms onset and randomization to no more than 7 days were included in the study. 8.Pyrexia (axillary > 98.6°F or frontal >99.5°F); or/and any of the

following symptoms having patients were included in the study: Cough, Sore throat, Headache, Nasal congestion, Body aches and pains, Fatigue, Patients who have the evidence with Loss of smell and Taste were included in the study and Pregnant or lactating women were not included in the study. The study experiment is mainly focused for RT-PCR test. The Investigational (Test) products "Earth Tea" were stored in refrigerator as per product label instructions received from the sponsor and The study was conducted at Primary Health Care Centre, Kunigal, Karnataka India.

Statistical Analysis:

The statistical evaluation were performed by using Chi square test. Statistical analysis were performed using the latest version of SAS® system software (SAS Institute Inc., USA).

Results and Discussion:

Coronavirus disease 2019 (COVID-19) is a viral respiratory disease and causes inflammation of the mucosal membrane. This leads to alveolar damage and eventually pneumonia. It is caused by SARS-CoV-2, commonly known as novel coronavirus, a positive-sense single-stranded RNA virus. Earlier, coronaviruses have been reported to cause severe acute respiratory syndrome (SARS) and Middle East respiratory syndrome (MERS). Symptoms of COVID-19 like Fever, Dry cough, Tiredness, Sore throat, Diarrhea, Headache, Conjunctivitis, Nasal congestion, Body aches and pains, Fatigue, Loss of smell and taste, a rash on skin or discoloration of fingers or toes.

The present work was focused for clinical studies for the determinations of SARS-COV-2 (COVID-19) safety and efficacy of the new product "Earth Tea". Earth Tea is made of a combination of natural vegetable, Aloe Vera and Honey known to help to boosts our immune system. Earth Tea is 1-4 servings per bottle 16oz total with recommended servings of 8oz each, but 4oz can also be used. Earth Tea Extra Strength may be used to continuously boost our immune system, which may be used as 1 bottle every two weeks or at least one bottle per month to assist the immune system. Earth Tea might help with other issues where more than one bottle might be required per month in that case, 2 bottles max within 48 hours can be consumed with 8oz per serving every 8-10 hours. Earth Tea is all natural and might be hard to swallow because of the taste, it may be combined with juice and it will still be effective. Which mainly focused to increase the immunity level in human and helps to maintain the antioxidant levels which help to reduce the symptoms of COVID-19 infection. It is also helps in restoration of smell and taste.

Hence. An Open Label, Multicenter, Multi-Dose, Single Arm Treatment Clinical Trial in Human Adult Patients with Mild COVID-19 was the main goal of the study. To assess the safety and effectiveness of "Earth Tea" for COVID-19 as well as the safety and tolerability of a multi-dose given to human adult of patients with COVID-19 infections and approximately 15 patients were planned to be treated and analyzed for up to 10 days.

The study was divided into 3 Visits for a total of study Shown Figure-1: 1). Study Enrollment Visit (Day 00) 2). On therapy visit (Day 01) and 3). Evaluation Visit (Day 02). The duration of this study was 10 days (The study treatment duration was 04 to 05 days for each patient shown figure-2) from the day of check-in of first patient (05 Jul 21) to (14 Jul 21). The patients were given in the morning 08 Oz of cold tea will be administered orally and 08 Oz of Hot tea were administered after12 hours exactly two hours before bed.

Test product (T) in the first visit the dose was administered twice for day 01 in the clinical facility under the supervision of Investigators.

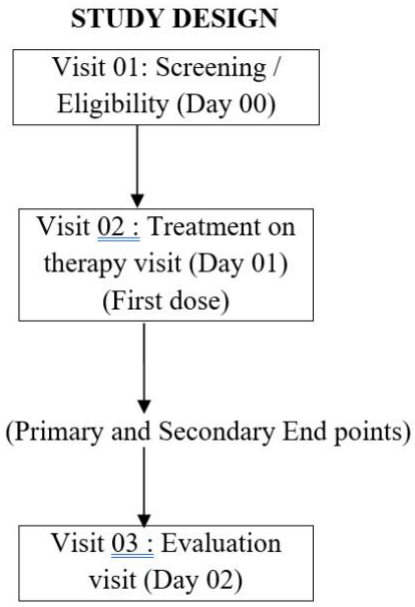


Figure-1: Shown The clinical trial study design

In the analysis, patients showed a significant result in Clinical cure and Microbiological cure efficacy analysis on Day 02 (End of Study). Demographic data, medical and medication history, physical examination and RT-PCR were did prior to study enrolment. The

Documentation of CT-Chest for available patients were collected before to study enrolment. The Informed consent (ICD) were read and signed prior to the study specific procedures before enrollment of all the patients. And additionally, urine pregnancy test was performed at each visit of the study. On the day of enrollment visit (Day 00) following list of procedures were done to the all patients.

i. Obtaining the ICD
ii. Inclusion and Exclusion criteria compliance has verified
iii. Medical and Medical history was collected
iv. RT-PCR was done
v. Physical examination and vitals performed as per the protocol
vi. Safety evaluation and Monitoring for AE were done.

On day of therapy visit (Day 01) dosing was done as per the protocol. Safety evaluation and Monitoring for AE were done for all patients. On the day of evaluation visit (Day 01) following list of procedures was did as per the protocol.

i. RT-PCR was done
ii. vitals performed as per the protocol
iii. Safety evaluation and Monitoring for AE were done
iv. Efficacy evaluation was done as per the protocol

All the procedures and tests has been done in the clinical facility under the supervision of the Investigator on dosing day (Day 00) to Evaluation visit (Day 02) and AE were monitored. The quality of life was assessed by the questionnaires.

Therapeutic efficacy was determined based on the cure and Microbiological cure efficacy analysis on Day 02 (End of Study) and Microbiological cure efficacy analysis on Day 02. The Clinical cure was maintained up to 48 hours, Patients respond or not to treatment, based on the efficacy evaluation on the Day 02 for clinical cure and microbiological cure. After Day 02 Patient was continued with Standard Treatment based on the discretion of Investigator. The evaluation of product tolerance and nature of side effects also were summarized. Totally 15 generally human adult, patients with mild COVID 19 were enrolled and completed the study.

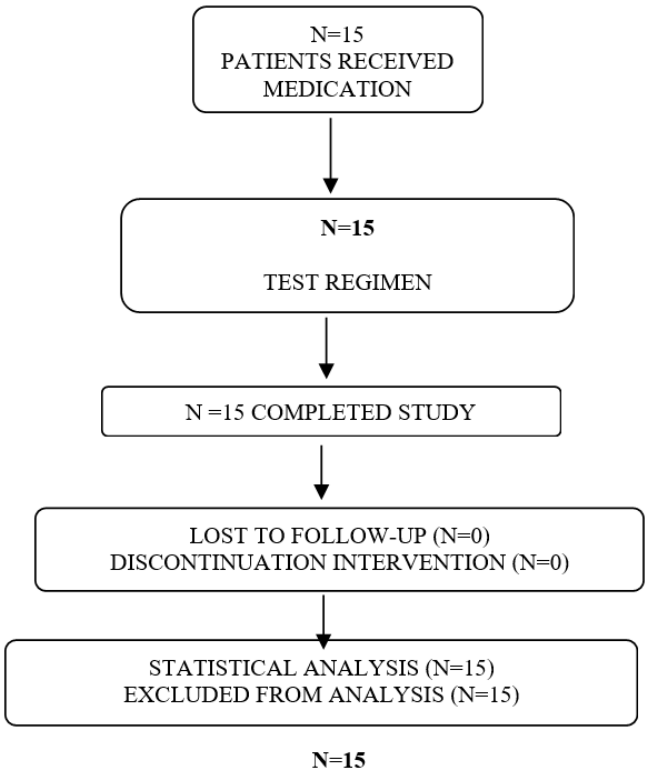


Figure-2: Patients Enrollment and Summaries

The product is a Earth Tea Manufactured By Martin Sinclair B4B Corp, 40, Remsen Ave, Brooklyn, NY 11212, United States and there is no deviation in this study. The Population analysis set included all enrolled patients who were exposed the treatment. A total of 15 patients were enrolled into the study and their mean age was 43 years respectively and All patients included in the study were Asian were shown on Table-1. The test investigational drug a product was administered to the patients at time of dosing and there was no deviation in drug dosing.

Table 1: Summarized Demographic Profile of Patients

Demographic details of patients who were participated and completed in the study (N=40)					
Parameter	**Mean**	**SD**	**Min**	**Max**	**CV%**
Age (years)	43	11.45	23.00	64.00	26.41

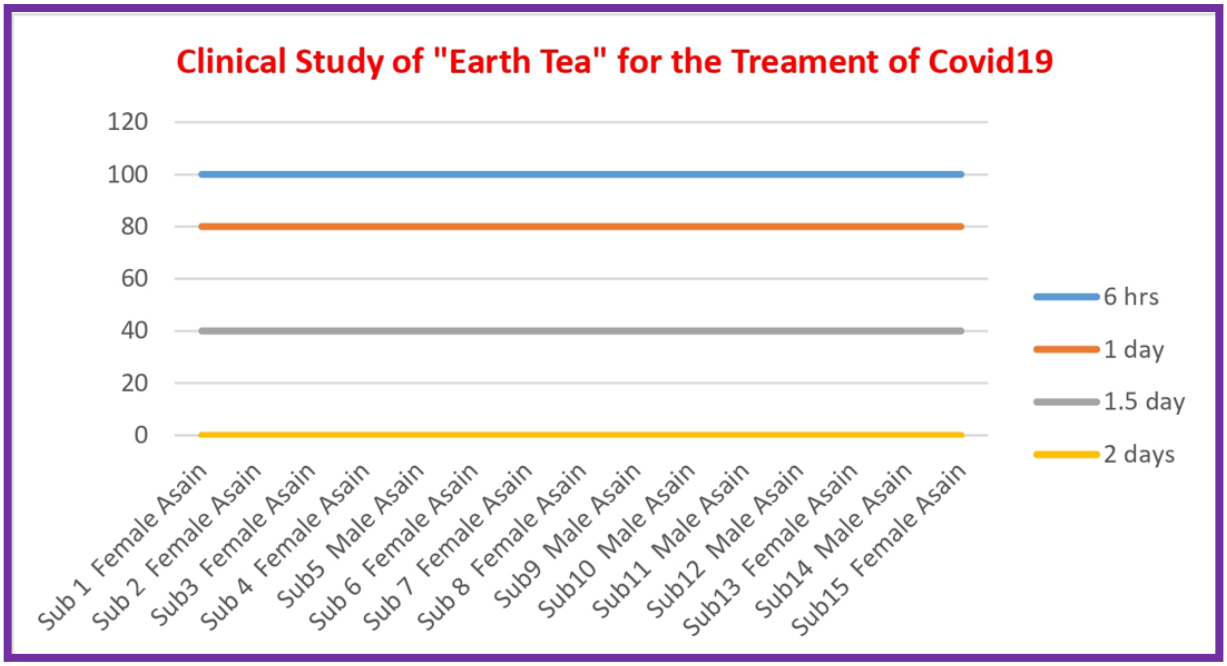
In the patients showed a significant result in their respond to treatment based on the efficacy evaluation on Day 02. The Data were reported as clinical cure and microbiological cure efficacy evaluation on Day 02. The lineal cure has maintained up to 48 hours. Safety data was summarized and tabulated and depending on the number of observations, a decision was made

whether to test the significance of any values. The data from 15 Patients who completed the study received test product were considered to perform the Efficacy analysis and its applicable for multicenter study. Hence, the data of 15 patients were considered to perform statistical analysis. The Individual RT-PCR report for all patients were generated.

In efficacy study, the data from 15 Patients who received the Investigational drug and completed the study were considered to perform the Statistical analysis by using the latest version of SAS® system software (SAS Institute Inc., USA). In the analysis, patients showed a significant reduction in clinical cure and micro biologically cure analysis on Day 02 of evaluation visit. Moreover, significant reduction in the RT-PCR report noted on Day-02. Hence, we can conclude that drug is showing very good results on Day-02 of evaluation visit. There were no adverse events reported during course of the study. Therefore, there were no Serious adverse events or deaths reported in this study.

During the course of study at every visit, blood Pressure, radial pulse rate, oral temperature and wellbeing status were enquired and recorded. RT-PCR were done on the day of before enrollment. Available CT-Chest documentation was collected. Therefore, were no variations on obtained.

Based on these results obtained in the study, the product is an Earth Tea Manufactured by Martin Sinclair B4B Corp, 40, Remsen Ave, Brooklyn, NY 11212, United States was found to have a significant efficacy and also a safe product Shown Graph-1 and Table-2.



Graph-1: Shown the RT-PCR Results of Each Results: X-axis Indicating The Subjects of 15 Asian Human Voluntaries, Y-axis Indicating the RT-PCR Effect of Each Subjects based on 6hrs, 1-Day, 1.5-Day and 2-Days (48 Hrs). The Earth Tea having the Significant Efficay of COVID-19 (Nagative).

Table 2: Individual demographic data of all patients (N=15) enrolled in the study

Subject No	Age (yrs)	Gender	Race	Smoking status	Results
1	34	Female	Asian	Non-smoker	Safe and significant Efficacy
2	29	Female	Asian	Non-smoker	Safe and significant Efficacy
3	30	Female	Asian	Non-smoker	Safe and significant Efficacy
4	30	Female	Asian	Non-smoker	Safe and significant Efficacy
5	21	Male	Asian	Non-smoker	Safe and significant Efficacy
6	60	Female	Asian	Non-smoker	Safe and significant Efficacy
7	55	Female	Asian	Non-smoker	Safe and significant Efficacy
8	38	Female	Asian	Non-smoker	Safe and significant Efficacy
9	27	Male	Asian	Non-smoker	Safe and significant Efficacy
10	25	Male	Asian	Non-smoker	Safe and significant Efficacy
11	32	Male	Asian	Non-smoker	Safe and significant Efficacy
12	32	Male	Asian	Non-smoker	Safe and significant Efficacy

Subject No	Age (yrs)	Gender	Race	Smoking status	Results
13	28	Female	Asian	Non-smoker	Safe and significant Efficacy
14	33	Male	Asian	Non-smoker	Safe and significant Efficacy
15	35	Female	Asian	Non-smoker	Safe and significant Efficacy

Conclusion:

The findings of this study clearly suggest that the Earth Tea manufactured by Martin Sinclair B4B Corp at 40 Remsen Avenue, Brooklyn, New York 11212, USA, is effective in reducing COVID-19 levels significantly when patients report their RT-PCR results. The analysis showing that the product is statistically effective. According to the data, patients displayed a substantial difference between their enrollment visit on day one and their evaluation visit on day two. As a result, we can say that the medicine is producing excellent outcomes as of the second day of the evaluation visit. All patients had a very positive experience with the medication of the product. Additionally, the patients weren't very concerned about any potential side effects, dosage restrictions, or their regular lives. Since none of the adverse events occurrences were determined to be caused by the study medicine of the product, Hence, the product's safety was amply demonstrated.

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