Clinical Trial Details (PDF Generation Date :- Wed, 07 Jun 2023 17:32:26 GMT)

CTRI Number	CTRI/2020/12/029735 [Registered on: 11/12/2020] - **Trial Registered Prospectively**
Last Modified On	13/05/2021
Post Graduate Thesis	No
Type of Trial	Interventional
Type of Study	Ayurveda
Study Design	Randomized, Parallel Group Trial
Public Title of Study	A Study to Assess the Safety and Efficacy of CoroQuil-Zn 750 in Comparison to the Standard of Care for the Treatment of Mild to Moderate COVID-19.
Scientific Title of Study	An Open-Label, Two-Arm, Parallel Design, Prospective, Single-Center, Phase 3 study to assess the safety and efficacy of CoroQuil-Zn in comparison to the standard of care for the treatment of mild to moderate COVID-19

Secondary IDs if Any

Secondary ID	Identifier
NIL	NIL

Details of Principal Investigator or overall Trial Coordinator (multi-center study)

Details of Principal Investigator	
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Designation	Principal Investigator
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Details Contact Person (Scientific Query)

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Source of Monetary or Material Support

Source of Monetary or Material Support
> Remedium Therapeutics Private Limited

Primary Sponsor

Primary Sponsor Details	
Name	Remedium Therapeutics Private Limited
Address	No.1320 2nd floor 33rd street 7th sector KK Nagar Chennai Tamil Nadu
Type of Sponsor	Pharmaceutical industry-Indian

Details of Secondary Sponsor

Name	Address
Remedium Therapeutics Private Limited	No.1320 2nd floor 33rd street 7th sector KK Nagar Chennai Tamil Nadu

Countries of Recruitment

List of Countries
India

Sites of Study

Name of Principal Investigator	Name of Site	Site Address	Phone/Fax/Email
Dr Sambashiva AC	Sri Lakshmi Super Speciality Hospital	Sri Lakshmi super speciality hospital, Department of General Medicine No. 5,6,7, 1st cross, Kaggadasapura main Rd, nagappareddy layout, C V Raman Nagar, Bengaluru, Karnataka 560093 Bangalore KARNATAKA	6364147979 info@samahitha.com

Details of Ethics Committee

Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
PRANAV DIABETES CENTER ETHICS COMMITTEE	Approved	03/12/2020	No

Regulatory Clearance Status from DCGI

Status	Date
Not Applicable	No Date Specified

Health Condition / Problems Studied

Health Type	Condition
Patients	Coronavirus as the cause of diseases classified elsewhere

Intervention / Comparator Agent

Type	Name	Details
Intervention	CoroQuil-Zn 750mg	750mg x 2, administered orally three times a day for 14 days
Comparator Agent	COVID Standard Care	As per the sites COVID SOP

Inclusion Criteria

Inclusion Criteria	
Age From	18.00 Year(s)
Age To	75.00 Year(s)
Gender	Both
Details	1. Written signed and dated informed consent (patient or LAR). 2. Both genders, aged ?18 to ?75 years, 3. Patients with RT-qPCR confirmed COVID-19 patients 4. SpO2?90% and

	respiratory rate ?30/minute 5. Healthy adult patients with ASA I to II 6. A score of between 3 to 5 on the Modified WHO Ordinal Scale for Clinical Improvement (refer protocol appendix 23.1) 7. Patients who agree to abide by the study requirements

Exclusion Criteria

Exclusion Criteria	
Details	1. Pregnant and lactating women 2. Children 75 years 3. SpO230/minute 4. Patients having persistent nausea/vomiting 5. Need for direct admission to the intensive care unit for mechanical ventilation 6. Underlying chronic obstructive pulmonary disease stage III-IV 7. Patients simultaneously participating in another clinical study. 8. History of stroke with significant neurologic deficit. 9. Patients with any concurrent pre-existing severe/uncontrolled, clinically significant systemic disease [e.g. heart failure (NYHA 2 or above)], cancer, liver disease, kidney disease or anaemia etc.) that, in the opinion of investigator precludes the subject's participation in the study or interferes with the interpretation of the study results. 10. Patients with history of serology tests positive for hepatitis B, hepatitis C, or human immunodeficiency virus. 11. Medical or psychological conditions deemed by the investigators to interfere with successful participation in the study 12. A subject who is judged by the investigator as inappropriate to participate in the study for any reason other than those mentioned above.

Method of Generating Random Sequence	Coin toss, Lottery, toss of dice, shuffling cards etc
Method of Concealment	Not Applicable
Blinding/Masking	Open Label

Primary Outcome

Outcome	Timepoints
Negative result for qRT-PCR testing for COVID	14 days

Secondary Outcome

Outcome	Timepoints
percentage of patients showing negative qRT-PCR earlier than the End of study visit	day 5, day 7

Target Sample Size	**Total Sample Size=**100 **Sample Size from India=**100 **Final Enrollment numbers achieved (Total)=**114 **Final Enrollment numbers achieved (India)=**114
Phase of Trial	Phase 3
Date of First Enrollment (India)	15/12/2020
Date of First Enrollment (Global)	No Date Specified
Estimated Duration of Trial	**Years=**0 **Months=**4 **Days=**0
Recruitment Status of Trial (Global)	Not Applicable
Recruitment Status of Trial (India)	Completed
Publication Details	NIL
Brief Summary	This was an open-label, two-arm, parallel design, prospective, single-centre, phase 3 study to

assess the safety and efficacy of CoroQuil-Zn when compared to the Standard of Care [Mild cases: Azithromycin 500mg tab (once daily) + Corticosteroids (Twice daily) + Paracetamol (Twice daily) + Aspirin 500mg (Twice daily); Moderate Cases: Piperceillin tazobactum 4.5mg inj. or Ceftrixone 1gm inj.(Once daily) + Corticosteroid (Twice daily) + Enoxiparin 40 (Twice daily) + Paracetamol 650mg (Twice daily); IV infusion if required (only in case of weakness); All Antibiotics for 6 days and other medications based on the reports and PI discretion] for the treatment of mild to moderate COVID-19 infection.

- 120 patients screened and 114 randomized in this study.
- Both inpatients and outpatients were enrolled in this study.
- 57% males and 42% females were enrolled in this study.
- The median age group was 31 years in this study.
- The study drug was well-tolerated by the subjects and no adverse drug reactions were observed.
- There were no deaths reported in both the treatment groups.
- Clinical Response & Clinical Cure at the Day 7 visit: 98% of the patients in the CoroQuil-Zn group showed a clinical response when compared to the Standard of Care group (82%) which is statistically significant (p-value: 0.0035).
- The median time to Clinical Response & Clinical Cure was 3 days in the CoroQuil-Zn group and 6 days in the Standard of Care group which is statistically significant (p-value: <0.0001).
- Virological Cure at Day 7 visit: Majority of the patients in the CoroQuil-Zn arm (95%) and showed virological cure as compared to the Standard of Care group (59%) which is statistically significant (p-value: <0.0001).
- Virological Cure at Day 14 visit: Majority (97%) of the patients in the CoroQuil-Zn group showed virological cure when compared to the Standard of Care group (86%) which is statistically significant (p-value: 0.0372).
- The median time for Virological Cure was 6 days for the CoroQuil-Zn group and 7 days for the Standard of Care group which is a statistically significant (p-value: <0.0001).
- The severity of Dyspnea at the Day 7 visit: There is a significant reduction in Dyspnoea with CoroQuil-Zn group as compared to the Standard of Care group which is statistically significant (p-value: <0.0001).
- The severity of Dyspnea at the Day 14 visit: There is no significant reduction in Dyspnea with the CoroQuil-Zn group as compared to the Standard of Care group on Day 14.

- Baseline IL-6 levels compared to Day 7 & Day 14 visit: There is a statistically significant reduction in IL-6 levels at day 7 (p-value: <0.0001) & Day 14 (p-value: <0.0001) in the Coro*Q*uil-Zn group which is not seen in the Standard of Care group when compared to the baseline visit. There is statistically significant change seen between the two treatment groups at day 7 (p-value: 0.002) and day 14 visit (p-value: 0.0046) when compared to the baseline visit

- Baseline CRP, D-Dimer & Serum Ferritin levels compared to Day 7 & Day 14 visit: There is no statistically significant reduction observed between the two treatment groups at day 7 and day 14 visits when compared to the baseline visit.

- No clinically significant findings were observed in the physical examination, vitals, clinical laboratory tests, 12-lead ECG, chest X-Ray and routine urine analysis.

- A total of 05 adverse events (AEs) were reported in this study. All AEs were mild in severity, which resolved without sequelae.

Overall, at Day 7 visit in the Coro*Q*uil-Zn treatment group, a statistically significant Clinical response, Clinical cure, Virological cure and reduction in the severity of Dyspnoea was observed.

Conclusion:

During the primary analysis, a numerically higher positive trend was observed in the clinical response. Throughout the trial, a statistically significant improvement was seen in the Coro*Q*uil-Zn treatment group for Clinical response, Clinical cure, and Virological cure, reduction in the severity of Dyspnoea and recovery rate in the secondary analysis. The median time to Clinical response, Clinical cure, and Virological cure was also statistically significant in the Coro*Q*uil-Zn treatment group.

From the analysis of this trial data, it is evident that capsule Coro*Q*uil-Zn750 mg benefits mild to moderate COVID-19 patients. Administering Coro*Q*uil-Zn 750mg will reduce the patient load on the hospital, recovery at home and may fulfil the current unmet need during this ongoing pandemic.