Title of the study:

Positive case control study on analyzing the Supportive role of Koronaguard in COVID-19 management along with allopathic treatment.

Study conducted by

Frontier Mediville Research Park-SEZ

in collaboration with

Tamil Nadu Government Health & Family welfare

Frontier Mediville Team

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Study conducted at:
Medivelle Covid care,
Elavur Village,
Gummudipoondi Taluk
Thiruvalluvar District.

State Health Authorities
Dr. Jawaharlal DDH
Dr. Govindarajan BMO
Dr. Pari
Dr. Manoj -Health inspectors
Nurses

Population density: 1049 /sq km

Koronaguard Inverntors & Manufacturers:
Dr. Ramu & Mr. Krishnan, Sundar Chemicals, Dezire Sweets

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Study background:

The recent outbreak of novel coronavirus disease 19 (COVID-19), caused by highly contagious virion severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). As this virus gains entry through nasopharyngeal route, it has been reported globally that it transmits through aerosols released from infected persons. Most people infected with the COVID-19 virus will experience mild to moderate respiratory illness and recover without requiring special treatment. Older people and those with underlying medical problems like cardiovascular disease, diabetes, chronic respiratory disease, and cancer are more likely to develop serious illness. So far there is no clinically approved antiviral drug or vaccine available to treat or prevent the disease. Therefore, addressing the current medical emergency, we are in the dire need of therapeutic combination of medications that can offer treatment strategy to manage the disease or agents which can further prevent the viral entry until the vaccines are available commercially.

Aim of the study:

The aim of the study was to evaluate the efficacy of Koronaguard which could be given as supportive care along with the ongoing prescribed medication to manage the disease.

Objective of the study:

This study aims to evaluate the supportive role of "**Koronaguard**" –our proposed disease management medication using RT-PCR. The efficacy was evaluated in terms of comparative analysis of Ct (Cycle threshold value) between Koronaguard group and placebo control groups.

Product Description- Koronaguard:

Koronaguard is a preventive medication consisting the mixture of **natural oils such as hydrogenated castor oil, virgin coconut oil, peppermint oil, cinnamon oil and clove oil respectively**. Koronaguard oil mixture contain polyoxyl hydrogenated castor oil and edible virgin coconut oil acting as surfactant and actively solubilizes the viral lipid bi layer including spike protein. We anticipate these natural edible oil will effectively minimize the viral load of the person and reduce the severity of the chronic inflammatory response in host triggered as the result of the viral entry.

Manufacturers:

The products Koronaguard and placebos were formulated by Dr. K. Ramu and manufactured by Sundar Chemicals, C/O Dezire Sweets. The formulated products used in the study were formally approved by Food Safety and Standards Authority of India (*FSSAI*).

Materials and Methods:
Materials:

1. Koronaguard Group:

   ➢ Koronaguard Formulations-Nasal drops, Gargle and Lozenges.

2. Placebo Group:

   ➢ Saline Nasal drops, Warm water gargle and Orange candy.

Mode of application:

The mode of transmission in COVID-19 is through physical contact with the infected persons and through respiratory droplets or aerosols released by the infected person. We formulated the Koronaguard as nasal drops, gargle, and lozenges, in which the gargle and lozenges targets mainly the oro-pharyngeal airway and the nasal spray masks the nasal route.

Methodology:

1. This observational study evaluating the efficacy of Koronaguard was conducted in the Frontier Mediville COVID-19 care center at Elavur village, Gummudipoondi taluk, Thiruvallur district. Volunteers participating in the study were enrolled and the consent forms were obtained from them.

2. The prescribed medications for the Koronaguard and placebo groups were given with the products at regular intervals of thrice a day for three consecutive days (n=42 for Koronaguard & n=11 for placebo control).

4. The collected samples Ct value at Day 1 and Day 3 were obtained and tabulated in both Koronaguard and placebo control groups.

Results:

	Koronaguard group		
S.No	**Patient ID**	**Day 1**	**Day 3**
1	KG01	33.9	40
2	KG02	32.01	40
3	KG03	30.2	40
4	KG04	31.09	40
5	KG05	26.27	37.34
6	KG06	26.1	40
7	KG07	33.29	40
8	KG08	32.23	40
9	KG09	32.98	40
10	KG10	31.78	40
11	KG11	32.01	40
12	KG12	33.21	40
13	KG13	31.94	40
14	KG14	31.12	40
15	KG15	32.9	40
16	KG16	31.89	40
17	KG17	31.21	40
18	KG18	19.2	33.21
19	KG19	32.71	39.34
20	KG20	31.28	39.1
21	KG21	32.34	40
22	KG22	29.68	36.78
23	KG23	31.12	40
24	KG24	32.91	40
25	KG25	33.82	40
26	KG26	33.27	37.89
27	KG27	32.25	40
28	KG28	28.09	39.41
29	KG29	30.06	38.76
30	KG30	24.84	36.59
31	KG31	30.09	39
32	KG32	30.09	38.66
33	KG33	35.84	40
34	KG34	36.21	40
35	KG35	30.58	36.31
36	KG36	31.25	37.21
37	KG37	26.27	35.99
38	KG38	29.24	37.94
39	KG39	29.98	37.92

40	KG40	33.45	39.53
41	KG41	33.62	39.45
42	KG42	31.0322	39.03488
	Average	**31.01**	**39.03**
	SD	**3.09113**	**1.51**

Table 1: Tabulation of Ct values obtained from the COVID positive patients before and after 3 days of Koronaguard study.

Ct values description: Ct values 15 to 25- Strong positive, 25 to 30- Moderate Positive, 33 to 35- Mild positive, 35 to 40-Negative, >40- Undetermined or nil expression.

Placebo group			
S.No	**Patient ID**	**Day 1**	**Day 3**
1	PC01	27.01	30.52
2	PC02	32.96	34.79
3	PC03	31.59	33.21
4	PC04	32.43	34.69
5	PC05	32.57	33.59
6	PC06	30.01	33.96
7	PC07	31.96	34.12
8	PC08	31.43	34.91
9	PC09	33.64	35.25
10	PC10	32.91	34.99
11	PC11	31.52	34.25
	Average	**31.639**	**34.02545**
	SD	**1.81938**	**1.32079**

Table 2: Tabulation of Ct values obtained from the COVID positive patients before and after 3 days of Placebo control group.

KG versus PC Mean Ct value difference		
Group	**Mean Ct value**	
	Day 1	Day 3
Koronaguard	31.01	39.03
Placebo	31.639	34.025
Mean Ct value difference		**5.005**

Table 3: Tabulation showing Mean Ct difference compared between Koronaguard and Placebo control group.
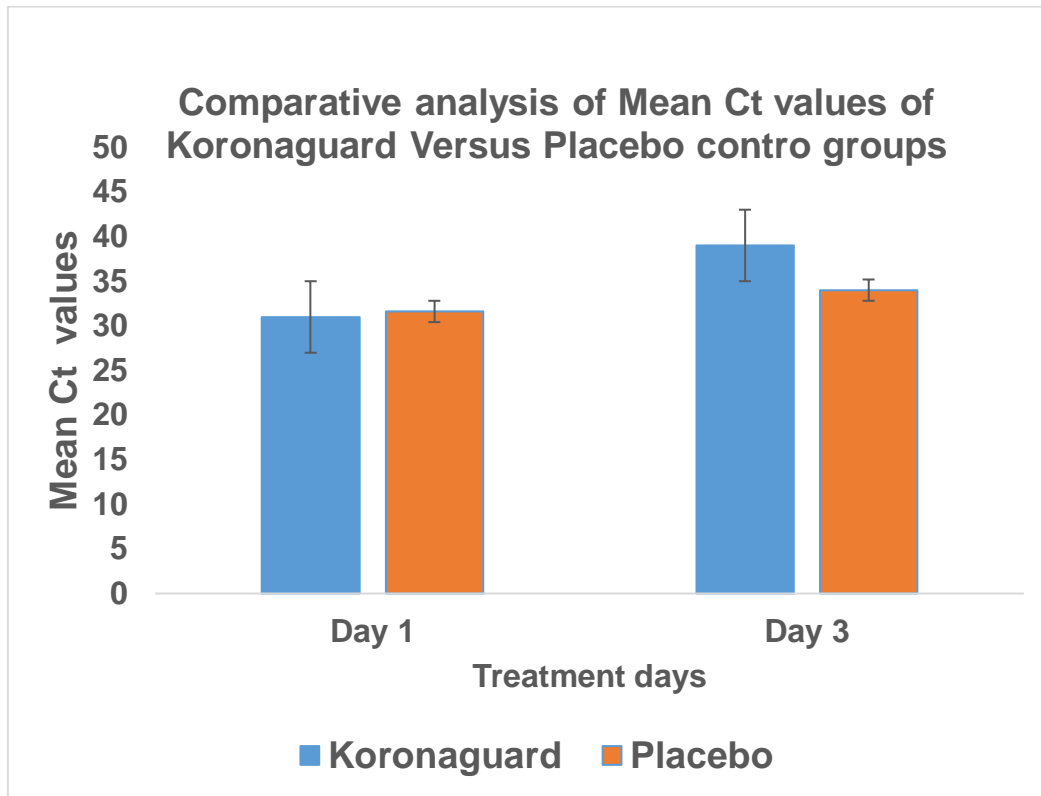
Figure 1- Bar graph representation of evaluated efficacy between Koronaguard and placebo controls.

Conclusion:

An average Ct value difference of 8.02 was observed during the treatment intervals on day 1 and day 3 with Koronaguard group. On the other hand, an average Ct value difference of 2.39 was obtained in Placebo group.

➢ **Comparatively a mean Ct difference of 5.005 was observed between Koronaguard and Placebo groups.**

➢ **In nutshell, the observational study in the normal COVID-19 positive patients showed the Koronaguard is 5 times more potent in reducing the viral loads with respect to the control groups (this inference was recommended on the basis of Ct values only).**

Discussion:

This is a new disease of unknown origin where no one has any knowledge about the disease manifestation and management. During 1820's, 1920's, a similar outbreaks such as Spanish flu had occurred where people followed isolation, wearing masks and social distancing to minimize the disease exposure. Hydroxychloroquine is being used nowadays to treat the new viral diseases like Zika virus. The rationale behind using this is that in the present pandemic of coronavirus disease (Covid-19), the drug is being repurposed based on its vitro evidence of efficacy against coronavirus. In other countries like US, the childrens above the age of 4 are vaccinated and are advised to put on their masks. **In our study also we have formulated the anti-corona agents composed of edible natural oils which targets the viral bi-lipid layer and kills it. The above study confirms the efficacy of Koronaguard as a supportive drug in the COVID-19 (without any co-morbidities). However, our study further recommends the *in vitro* anti-viral assay for generating a validated concrete profile for its virucidal effect.** In our country, we can give our children the lozenges and gargle until the vaccines are available as a preventive and supportive strategy for the management of disease. The gargle could be swallowed and the content will be internalized and absorbed by papillary absorption and thus providing the systemic protection.

With high warms & regards,

Dr.K.M.Cherian