RANDOMISED CLINICAL TRIAL TO ASSESS THE IMPACT OF ORAL INTERVENTION WITH CETYLPYRIDINIUM CHLORIDE TO REDUCE SARS-COV-2 VIRAL LOAD

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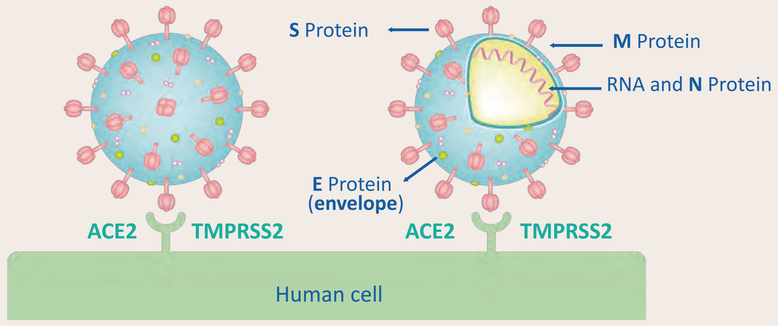
01 | BACKGROUND:

The oral cavity represents a potential source of **SARS-CoV2** infection. **SARS-CoV-2** binds to the receptors of angiotensin-converting enzyme 2 and the transmembrane protease serine 2 enzyme, which are highly expressed in the salivary glands, tongue and sulcular epithelium. The intervention, aimed at reducing the viral load in saliva through rinsing, may help control and reduce viral transmission and could be considered as a novel Public Health strategy.



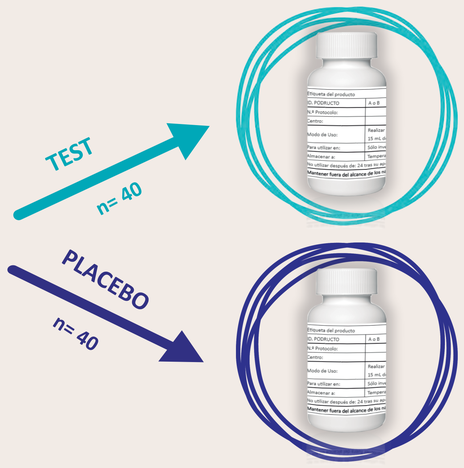
02 | AIM:

To determine the efficacy of cetylpyridinium chloride (CPC) mouthwashes in reducing the viral load of SARS-CoV-2 in the saliva of COVID-19 patients.

03 | MATERIAL AND METHOD:

80 SARS-CoV-2-positive patients were enrolled and randomly assigned to two groups: CPC intervention group (n = 40) and water control group (n = 40). **Inclusion criteria: SARS-CoV-2** -positive patients Symptom development up to 3 days, 18-80 years of age. **Exclusion criteria:** Patients with hyposialia. Patients who had used oral antiseptics (in the form of mouthwash containing CPC, rinses with povidone iodine, mouthwashes with alcohol and essential oils) and/or toothpastes with CPC in the month prior. Patients with cognitive and/or motor impairment. Pregnant women. Saliva samples were collected from the patients at the time of diagnosis and 2 hours after the application of CPC/water rinses. The samples were subjected to RT-PCR and ELISA assay.

The clinical trial was approved by the Clinical Research Ethics Committee of Aragon with the C.P. reference **CPC01- C.I. (Research Committee) EC20/0092.** It was registered on the **ClinicalTrials.gov** platform under reference number **NCT04820803.**



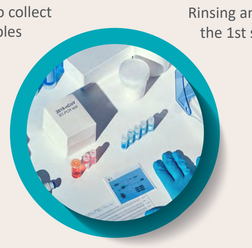
SARS-CoV-2 diagnosis. C.S. Seminar

Training, how to collect saliva samples

Rinsing and collection of the 1st saliva sample

Collection of the 2nd saliva sample at home after 2 hours

The saliva samples were kept frozen at -20°C

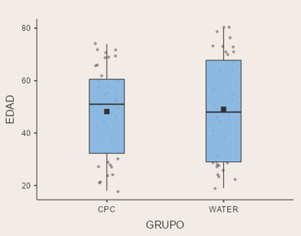


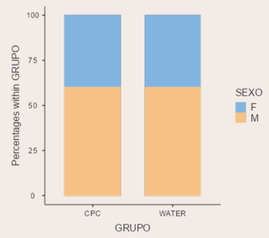
Analysis 160 samples RT-PCR technique. Hospital Clínico Universitario Lozano Blesa

Analysis 160 samples ELISA technique. IrsiCaixa Lab.

04 | RESULTS:

The average age of the patients was **48.6 years** (SD = 18.2) and **60% were male**, with no statistically significant differences between the two groups.





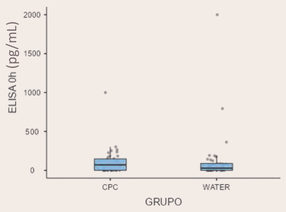
RT-PCR analysis using the ORF1ab sequence as a target; no statistically significant differences were observed when comparing the Ct values of both groups (WATER vs CPC) either at baseline (M1) or 2 hours after rinsing (M2).

Ct PCR	GROUP	Mean (SD)	IQR	p-value
ORF1ab M1	CPC	22.56 (3.85)	**22.80 (4.40)**	0.4771
	WATER	22.82 (5.04)	**23.45 (4.25)**	
ORF1ab M2	CPC	22.59 (3.19)	**23.40 (4.25)**	0.6696
	WATER	22.71 (5.08)	**22.95 (5.43)**	

RT-PCR analysis using the N gene as a target; no statistically significant differences were observed in this care either when comparing the Ct values of both groups (WATER vs CPC) either at baseline (M1) or 2 hours after rinsing (M2).

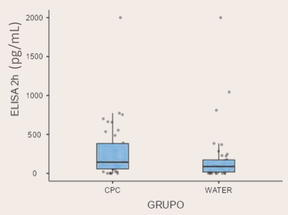
Ct PCR	GROUP	Mean (SD)	IQR	p-value
N M1	CPC	**25.27 (3.63)**	25.60 (5.00)	0.1401
	WATER	**26.45 (3.44)**	26.35 (4.13)	
N M2	CPC	**25.30 (3.00)**	25.90 (3.95)	0.2040
	WATER	**26.22 (3.37)**	26.15 (5.30)	

Analysis with the **ELISA** technique, no significant baseline differences were observed between the CPC and WATER groups at baseline (0 hours).



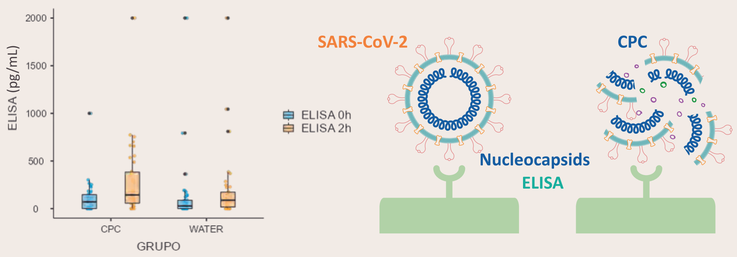
	GROUP	Average	IQR	p-value
ELISA 0h (pg/mL)	CPC	103	**70.46 (146.99)**	0,394
	WATER	123	**27.95 (87.76)**	

However, with the ELISA technique, 2h after rinsing, a significantly higher amount of nucleocapsids was observed in the CPC group compared to the control group.



	GROUP	Average	IQR	p-value
ELISA 2h (pg/mL)	CPC	288	**143.50 (326.25)**	0,038
	WATER	189	**87.76 (156.02)**	

Statistically significant differences were observed between the **ELISA** values measured at baseline and 2h after rinsing. The effect size is larger in the CPC group.



	CPC n = 39	WATER n = 39
ELISA 0h (pg/mL) Mean (SD)	103.16 (172.39)	122.55 (334.75)
ELISA 2h (pg/mL) Mean (SD)	288.43 (367.73)	188.76 (366.01)
Paired Samples T-Test p- value	0.0034	0.0122
Effect size (Cohen, 1988)	- 0.7	- 0.5

05 | CONCLUSIONS

The use of 0.07% CPC mouthwashes causes the degradation of the SARS-CoV-2 virus in the mouth of COVID-19-positive patients. The use of CPC mouthwashes can be useful to reduce viral load, which could help to decrease the transmission of the virus and lessen the symptoms of COVID-19.

Download Bibliography

ClinicalTrials.gov

Download Clinical Trial Protocol