Early nasal gel application in COVID-19 patients - RCT study

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FIRST TIME PRESENTER

Objectives:

Nasal mucosa target cells are prone to initial infection by SARS-Cov-2 viruses. Therefore, an oro-naso-pharyngeal care gel was applied via nasal application to (i) prevent inflammation, (ii) to compare clinical symptoms with conventional irrigation and - (iii) to correlate to the OHIP-G14 outcomes (German validation).

Material and Methods:

The randomized clinical trial was organized under the strict isolation conditions within the first 2 years of the COVID-19 pandemy. After ethical approval EK 66/2021 the test-group-A and the control-group-B comprised 25 SARS-CoV-2 positive COVID-19 subjects each. OROFAN® Gel in Group-A contains ChitoClear and 3 other bio-polymers, is moderately antibacterial and executes at mucosal cells a virus barrier for up to 16 hrs because of the long bioavailability (in-vitro testing Dr.Brill Institutes, Hamburg, Germany).

For 10 days the gel was applied in Test-Group A at home once or multiple times per day into the nostrils and distributed throughout the nose by slight finger pressure at the right and left nose site. A diary assessed 8 symptoms daily and 5 summarizing questions at day-10. Control-Group-B used a nasal douche with salt-water once or multi times per day. The protocol-B was the same as protocol-A. The Health-related Individual Profile OHIP-G14 was assessed at baseline and at the end of study. The statistics comprised the Mann-Whitney-U-test and ANOVA with the 95% confidence interval.

Results:

OHIP-14 deteriorated with non-significant results between both groups from pain-coding 39 to 48 because of severity of COVID-19. The mainly not changing all other Domains demonstrate that the OHIP-14 profile does not contribute to the characterization of SARS-Cov-2 infected subjets.

Nasal application of gel was statistically superior versus salt-water irrigation in 3 from 4 Likert items (application/irrigation, bioavailability, smelling). Descriptive analysis of diary symptoms revealed parallel improvement in A/B in days: **Percentage at End of Study in Likert scale and number of days from beginning:** Dry nose 52% vs. 60% and 4.7 vs. 6.2 days; Rhinitis 92% vs. 88% and 6.2 vs. 6.1 days; Dysgeusia 32% vs. 40% and 5.4 vs. 5.1 days; Headache 68% vs. 84% and 3.6 vs. 3.9 days; Abnormal fatigue 84% vs. 96% and 5.9 vs.4.7 days. Percentage of subjects and mean time duration evolved clinically parallelized. In contrast to this clinical symptoms with insignificant differences, the end of study evaluation of subjective perceptions revealed all items in favor of the Test-Group using the gel ones or many times per day: Mean Likert values in Test-Group A – 7.1 versus Control-Group B – 5.6.

Conclusions:

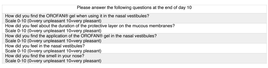
The OROFAN Oral Care Gel for nasal application contributes to nasal health in COVID-19 patients. It is better accepted compared to salt-water nasal douche and recommended for adjunctive treatment.

Fig. 1: Houfil Nasal douche (Wenzhou Zuoyou Medical Technology Co., Ltd., Wenzhou, China)

Fig. 2: OROFAN® Oral Care Gel for nasal application (Dr.Hinz Dental, Dr. Hinz Dental- Vetriebsgesellschaft mbH & Co. KG, Herne, Deutschland)

	Date	Fever above 38°C	Headache	Snort	Nasal Dryness	Fatigue	Shortness of breath	Loss of taste/sense of smell	Additional medication	Symptoms
	e.g. 01.02.2021	Yes/No	Yes/No	Yes/No	Yes/No	Yes/No	Yes/No	Yes/No	Yes/No, name medication	Other complaints not listed here
Day 1 – Day 10										

Fig. 3: Symptom diary for Test-Group A and Control-Group B

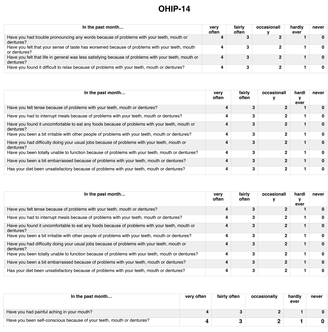


Please answer the following questions at the end of day 10
How did you find the OROFAN® gel when using it in the nasal vestibules?
Scale 0-10 (0=very unpleasant 10=very pleasant)
How did you feel about the effect of the protective layer on the mucous membranes?
Scale 0-10 (0=very unpleasant 10=very pleasant)
How did you find the application of the OROFAN® gel in the nasal vestibules?
Scale 0-10 (0=very unpleasant 10=very pleasant)
How did you feel in the nasal vestibules?
Scale 0-10 (0=very unpleasant 10=very pleasant)
How did you find the smell in your nose?
Scale 0-10 (0=very unpleasant 10=very pleasant)

Fig. 4: Summarizing questions at day 10, Test-Group A

Please answer the following questions at the end of day 10
How did you find using the nasal douche?
Scale 0-10 (0=very unpleasant 10=very pleasant)
How did you feel about the effect of the nasal douche?
Scale 0-10 (0=very unpleasant 10=very pleasant)
How did you find the salt water of the nasal douche in your nose?
Scale 0-10 (0=very unpleasant 10=very pleasant)
How did you find the application of the nasal douche?
Scale 0-10 (0=very unpleasant 10=very pleasant)
How did you find the smell in your nose?
Scale 0-10 (0=very unpleasant 10=very pleasant)

Fig. 5: Summarizing questions at day 10, Control-Group B



OHIP-14

In the past month...	very often	fairly often	occasionally	hardly ever	never
Have you had trouble pronouncing any words because of problems with your teeth, mouth or dentures?	4	3	2	1	0
Have you felt that your sense of taste has worsened because of problems with your teeth, mouth or dentures?	4	3	2	1	0
Have you felt that life in general was less satisfying because of problems with your teeth, mouth or dentures?	4	3	2	1	0
Have you found it difficult to relax because of problems with your teeth, mouth or dentures?	4	3	2	1	0

In the past month...	very often	fairly often	occasionally	hardly ever	never
Have you felt tense because of problems with your teeth, mouth or dentures?	4	3	2	1	0
Have you had to interrupt meals because of problems with your teeth, mouth or dentures?	4	3	2	1	0
Have you found it uncomfortable to eat any foods because of problems with your teeth, mouth or dentures?	4	3	2	1	0
Have you been a bit irritable with other people of problems with your teeth, mouth or dentures?	4	3	2	1	0
Have you had difficulty doing your usual jobs because of problems with your teeth, mouth or dentures?	4	3	2	1	0
Have you been totally unable to function because of problems with your teeth, mouth or dentures?	4	3	2	1	0
Have you been a bit embarrassed because of problems with your teeth, mouth or dentures?	4	3	2	1	0
Has your diet been unsatisfactory because of problems with your teeth, mouth or dentures?	4	3	2	1	0

In the past month...	very often	fairly often	occasionally	hardly ever	never
Have you felt tense because of problems with your teeth, mouth or dentures?	4	3	2	1	0
Have you had to interrupt meals because of problems with your teeth, mouth or dentures?	4	3	2	1	0
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Have you been totally unable to function because of problems with your teeth, mouth or dentures?	4	3	2	1	0
Have you been a bit embarrassed because of problems with your teeth, mouth or dentures?	4	3	2	1	0
Has your diet been unsatisfactory because of problems with your teeth, mouth or dentures?	4	3	2	1	0

In the past month...	very often	fairly often	occasionally	hardly ever	never
Have you had painful aching in your mouth?	4	3	2	1	0
Have you been self-conscious because of your teeth, mouth or dentures?	4	3	2	1	0

Fig. 6: Original version of OHIP-14 (Slade, 1997), for German subjects the Validated German Version OHIP-G14 (John et. al., 2006) was used.

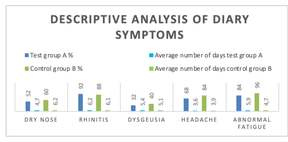

Fig. 8: Evaluation of the symptom diary of the Test Group A and Control Group B and average duration of the respective symptoms.

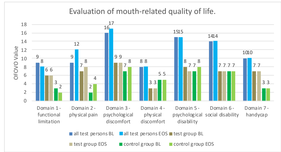

Fig. 9: Evaluation of the mouth-related quality of life on the basis of the OHIP-G14 questionnaire. The OFOVO coding (4 – 3 – 2) clearly shows, that there are all Domains with insignificant outcomes.

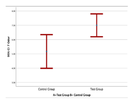

Fig. 10: End of the study: Significant Likert difference in odor of the Gel Group (Treatment), compared to the nasal douche.

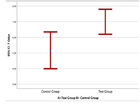

Fig. 11: End of the study: No significant Likert difference in the feeling of a protective layer of the Gel Group, compared to the effect of the nasal douche.

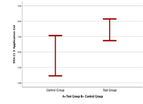

Fig. 12: End of the study: Significant Likert difference in the perception of using the Gel, compared to the nasal douche.

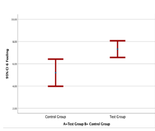

Fig. 13: End of the study: Significant Likert difference in the feeling of the Gel, compared to the nasal douche.