PARTICIPANT INFORMATION SHEET AND CONSENT FORM

RESEARCH INFORMATION

Protocol Title:

Efficacy of commercial mouth- rinses on SARS-CoV-2 viral load in saliva: randomized control trial in Indonesia

Principal Investigator:
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PURPOSE OF THE RESEARCH STUDY

Subjects were invited to participate in this research. Before participating, this research will be explained and the subject is given the opportunity to ask questions. Please read carefully the information provided here. If the subject agrees to participate, a informed consent will be signed. Subjects will be given a copy of this document to take home.

The objective of this study was to evaluate the virucidal effectiveness (lethal and destroy viruses) of commonly used commercial mouthwashes, such as Betadine mouthwash (Povidone-Iodine (PVP-I)), Oxyfresh (Sodium chlorite ($NaClO_2$)) and Pepsodent Active Defense (Cetylpyridiunium chloride (CPC)) to prevent the spread of COVID-19 through saliva.

We hope to study the effectiveness of Betadine, Oxyfresh and Pepsodent Active Defense mouthwashes in reducing the viral load of SARS-CoV-2 (name of the COVID-19 virus) in saliva. This study will provide evidence regarding the use of mouthwashes to minimize or reduce the viral load in saliva of infected patients and thereby help reduce transmission of COVID-19.

The subjects selected in this study were patients who were clinically diagnosed with COVID-19 (CT-value <30). This study recruited 68 positive COVID-19 patients from YARSI Hospital, Jakarta.

STUDY PROCEDURES AND VISIT SCHEDULE

If the subjects agreed to participate in this study, they were randomly assigned to receive Betadine, Oxyfresh and Pepsodent Active Defense mouthwashes or water (control group). Randomly assigned means placing the subject into one of 4 groups at random, such as tossing a coin or rolling a dice. Subjects will also be asked to provide saliva samples as part of this study. Participants in this study only took one visit to do the study.

Subjects will be asked not to eat, drink, or perform oral hygiene procedures for at least 30 minutes before saliva collection. Saliva will be collected after gargling with the spit method. Then the subject will be asked to rinse with a mouthwash. Saliva samples will be taken again at 5 minutes, 3 hours and 6 hours after rinsing.

We also asked for the subject consent to collect clinical data, such as details of COVID-19 diagnosis for research purposes. All data obtained during this research will be stored and only used for the purposes of this research.

All biological material (saliva samples) obtained in this study will be stored and analyzed in the Pathology Laboratory of YARSI Hospital and MiCORE Laboratory, Faculty of Dentistry, Trisakti University for research purposes.

In addition, human biological samples and data collected during the study will be retained for future research after the study is completed. For this purpose, consent for further research will be requested from the subject.

Visits and procedures:

Baseline (before rinsing): Rinse mouth, collect 3ml of saliva (approximately 10 minutes).

5 minutes after rinsing with mouthwash, collect 3ml of saliva (approximately 10 minutes).

3 hours after rinsing with mouthwash, collect 3ml of saliva (approximately 10 minutes).

6 hours after rinsing with mouthwash, collect 3ml of saliva (approximately 10 minutes).

RESPONSIBILITY OF THE SUBJECT IN THIS RESEARCH

If the subject agrees to participate in this research, they must do the following steps:

- Follow the advice given by the research team.
- Informing the main researcher as soon as possible about the side effects experienced.
- Prepare to undergo all procedures described above.

WHAT IS NOT THE PART OF STANDARD CARE OR EXPERIENCE IN THIS STUDY

This research was conducted because we wanted to know the effectiveness of the mouthwash solution in reducing the viral load in saliva. We hope that participants can help to understand whether the mouthwashes can be used to reduce the spread of COVID-19 through saliva.

POSSIBLE RISK AND DISCOMFORT

There was no potential risk to subjects when collecting saliva, as this method is a non-invasive method. The risk of breach of confidentiality will be minimized by ensuring that all information obtained from the subject remains confidential and only used for research purposes. Samples will be stored, secured and identifiable only by code number and separate from the subject identifying information.

POTENTIAL BENEFITS

Subjects will get the benefits from mouthwash in general. If proven effective, the use of these virucidal mouthwashes can immediately be incorporated into current infection control systems, along with washing hands and wearing masks. We hope that our research findings will help national efforts to curb the spread of COVID-19 in dental clinics and beyond. Participation of subjects in this study can increase medical knowledge about the effectiveness of mouthwash against SARS-CoV-2, as well as the use of mouthwash to prevent the spread of COVID-19 through saliva.

COSTS OF PARTICIPATION

If you take part in this study, the following will be performed at no charge to you:

- Collection of saliva samples

If you take part in this study, you will have to pay for the following:

- All relevant tests/medications which your doctor requested as part of your standard care

This study does not involve any payment to participants for participating in the study.

THE RIGHTS OF SUBJECT

The subjects in this study were completely voluntary. The questions submitted will be answered clearly and to the satisfaction of the subject.

If any new information becomes available relating to the subject willingness to continue the research, the subject (or his legal representative, if relevant) will be notified as soon as possible by the main researcher or his representative and further consent if necessary.

Biological samples collected for research will be given to YARSI Hospital. Subjects give up their rights to biological samples and any intellectual property rights that may be obtained from the use of such biological samples.

By signing and participating in research, the subject does not waive his legal right to withdraw consent and withdraw from the research at any time.

WITHDRAW FROM THIS STUDY

Subjects are free to withdraw consent and discontinue participation at any time without adversely affecting or impacting the subject medical treatment. If the subject decides to stop taking part in the study, he/she should notify the main researcher.

However, the data that has been collected up to the time of the subject resignation will be stored and analyzed. The reason is to allow a complete and comprehensive research evaluation.

Biological samples collected for this study will be given to the researcher and will not be returned to the subject. However, subjects retain the right to request that the main researcher discard or destroy the remaining samples if they have not been anonymized / individually identifiable and have not been used for current or future research or have been used for research but have discontinued further use.

The main researcher may discontinue the subject participation in the study at any time for one or more of the following reasons:

- ❖ Failure to follow instructions from the main researcher or research staff.
- ❖ Subject requires treatment which is not allowed in the research.
- ❖ Research canceled.

RESEARCH RELATED INJURIES AND COMPENSATION

If the subject follows the main researcher instructions of the study and is injured by the experimental substance or research procedure provided under the research plan, our institution will provide the appropriate medical care.

The subject still has all legal rights. Nothing is described in this study regarding treatment or compensation in any way that can change the subject right to recover damages if the subject can prove negligence.

CONFIDENTIALITY OF RESEARCH AND MEDICAL RECORDS

Participation of subjects in research will involve the collection of personal data. The personal data collected for this study will be kept confidential. Subject data, to the extent applicable laws and regulations, will not be made available to the public. Only researchers have access to the classified information collected.

By signing the informed consent, the subject agrees to: the collection, access, use and storage of personal data by researchers. "Personal Data" means data about a subject that makes himself identifiable: (i) from that data or (ii) from such data and other information to which an organization can or is likely to have access. The examples of personal data are medical conditions, medications, investigations, and medical history. Future research, based on this

"Personal Data", will be reviewed by the relevant institutional review board. The data collected is the property of the researcher. In the case of publication of this research, the identity of the subject will be kept in secret.

WHO TO CONTACT IF THE SUBJECT HAS QUESTIONS ABOUT THE RESEARCH

If the subject has any questions about the study or in any case of injury during the study, the subject may contact the main researcher:

Armelia Sari Widyarman, Ph.D. at +62811-929379

WHO HAS REVIEWED THE STUDY

This research has been reviewed by the Ethics Committee for Health Research, Faculty of Dentistry, Trisakti University and the Ethics Committee for Health Research at YARSI Hospital for ethical approval.

If the subject has feedback about this research, then they can contact the main researcher or the Ethics Committee for Health Research, the Faculty of Dentistry, Trisakti University and the Ethics Committee for Health Research at YARSI Hospital.

SERIOUS ADVERSE EVENTS

In the event of Serious Adverse Events, the procedures to be performed are:

1. Researchers will record all patient complaints related to drug side effects and asked about allergy history in the subject.

2. Researchers will report to the main researcher about the complaints experienced by the subject.

3. The researchers will continue the instructions from the main researcher for follow-up on the safety and comfort of the subject.

4. Researchers will recommend to the subject if there are still complaints experienced, immediately report to the nearest hospital for immediate follow-up.

5. Researchers will be responsible and bear all the costs of treatment for side effects caused by this study.

INFORMED CONSENT

RESEARCH DETAILS

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I agree to participate in this research, as described and the requirements set out in the Subject Information Form.

I have discussed and fully understood the aims and procedures of this research. I have been given a Subject Information Form and the opportunity to ask questions about this research and get satisfactory answers and information.

I understand that my participation is voluntary and I am free to resign at any time, without giving any reason and without affecting my medical treatment.

By participating in this research, I confirm that I have read, understood and agreed to the terms and conditions that apply.

I, the undersigned below:

Name :

Gender :

Place/Date of Birth :

Jakarta, _____ 2021

Witness	**Subject/Patient**
_____	_____
(Name)	*(Name)*

Consent to be re-identified and informed of unexpected findings

As previously explained, there may be potential unexpected findings that emerged in this study.

Please fill in whether you allow to be re-identified and informed of unexpected findings:

☐ **Yes, I agree** to be re-identified and informed if there are unexpected findings in this study. I can be reached at:

Phone:

If I can not be reached, please contact the following person I chose:

Name : _____

Phone : _____

☐ **No, I do not agree** to be re-identified and informed if there are unexpected findings in this study. (*You may want to note that in special situations such as life-threatening unexpected findings with available treatment options, we can contact you to confirm your decision whether to learn more about unexpected findings.*)

Consent for the use of data on future research

	Please fill in according to your answer by making a mark (√) in the available column :	**Yes**	**No**
	Will you agree if your data is used in future research?	☐	☐
	Note: If you answered "Yes" to the above question, please fill in the following questions:		
1.	Will you agree if your data is used for future research, involving humans and animals (eg limited human biomedical research)?	☐	☐
2.	Will you agree if your data was sent outside Jakarta for future research?	☐	☐
3.	Do you agree to be re-identified and informed if there are unexpected findings in this research? Note: If you answered "Yes", please fill in the statement below: I can be reached at: Phone/Email: If I can not be reached, please contact the following person I chose: Name: Phone/Email: *Note: You may want to note that in special situations such as life-threatening unexpected findings with available treatment options, we can contact you to confirm your decision whether to learn more about unexpected findings, even if you answered "No".*	☐	☐

Name	Signature/Thumbprint (Right/Left)	Date
_____	_____	_____

To be filled in by parents / guardian / legal representative, if required

I hereby give consent for the above subject to participate in the proposed research. The nature, risks and benefits of this research have been explained to me and I fully understand them.

I confirm that I have read, understood and agreed to the terms and conditions that apply.

_____	_____	_____
Name of Parents/Guardian/legal representative	Signature/Thumbprint (Right/Left)	Date

To be filled in by translators, if required

This research has been explained to subjects / legal representatives in:

_____ by _____.

Language Name of Translator

To be filled out by witnesses, if required

I, the undersigned, declare that:

- □I am 21 years or older.
- □Based on my knowledge, the subject or legal representative who signed this informed consent has been fully explained in a language that is understood by him and clearly understands the nature, risks and benefits of his participation in this research.
- □I have taken reasonable steps to ascertain the identity of the subject or legal representative providing consent.
- □I have taken steps to ensure that consent is given voluntarily without coercion or intimidation.

Witnessed by: _____ _____

Name Date

_____

Signature

1. An impartial witness (who is 21 years of age or older, has mental capacity, is independent from the research, and cannot be unfairly influenced by the people involved in the research) that must be present during all informed consent discussions if a subject or legal representative cannot read, and/or cannot sign or date the informed consent (using the subject or legal representative thumbprint). After the informed consent and any written information provided to the subject have been read and explained to the subject or legal representative, and after the subject or legal representative has verbally agreed to the subject participation in research and, if able to do so, has signed and personally dated the informed consent, the witness must sign and personally date the informed consent. This applies to clinical trials regulated by HSA and Human Biomedical Research under HBRA.

2. For HBRA research, witnesses can become members of the team conducting the research only if the subject or their legal representative can read, sign and date the informed consent.

Researcher Statement

I, the undersigned, certify that based on my knowledge, the subject / legal representative who signed the informed consent has been explained and fully understands the nature, risks and benefits of this research.

_____	_____	_____
Researcher Name	Signature	Date