University of Wisconsin-Madison
Consent to Participate in Research
and
Authorization to Use Protected Health Information for Research

Study Title: Role of naSo-oropHaryngeal antIseptic dEcolonization to reduce covid-19 viraL shedding and Disease transmission: SHIELD Study

Principal Investigators: Nasia Safdar, MD, PhD and Daniel Shirley, MD

Where Principal Investigators work: Department of Medicine, University of Wisconsin-Madison School of Medicine and Public Health

Participant Name: _____

Invitation

We invite you to take part in a research study about the use of povidone iodine (PI) and chlorhexidine gluconate (CHG), common treatments used in healthcare to prevent infections. We are studying whether using PI in the nose and CHG in the mouth can reduce transmission of the SARS-CoV-2 virus (the virus that causes COVID-19). We are inviting you because you are an essential worker who performs some of their job duties in person.

The purpose of this consent and authorization form is to give you the information you need to decide whether to be in the study. It also explains how health information will be used for this study and for other research in the future, and requests your permission to use your health information. Ask questions about anything in this form that is not clear. If you want to talk to your family and friends before making your decision, you can. When we have answered all your questions, you can decide if you want to be in the study. This process is called “informed consent.”

Why are researchers doing this study?

The purpose of this research study is to evaluate if the use of nasal povidone iodine (PI) and oral chlorhexidine gluconate (CHG) may reduce 1) SARS-CoV-2 virus and 2) COVID-19 diagnoses in participants using PI and CHG. We are doing this research because essential workers who cannot work remotely may be exposed to the virus from coworkers and members of the public. PI and CHG are regularly used for infection prevention for patients in healthcare, and have been shown to kill coronaviruses including SARS-CoV-2 on surfaces. We aim here to evaluate if using antiseptics (PI and CHG) as antiseptic treatments in essential workers’ noses and mouths is feasible and

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University of Wisconsin – Madison

effective in reducing SARS-CoV-2 viral transmission. If so, PI and CHG may be a useful addition to standard infection control equipment and procedures for essential workers (like handwashing and wearing face masks).

This study is being done at the University of Wisconsin-Madison. A total of about 250 people will participate in this study.

Am I eligible to participate in this study?

The study involves topical application of povidone-iodine in your nose and using CHG oral rinse as a mouthwash. The researchers need to verify whether you are eligible to participate by asking several questions below:

1. Do you currently have a diagnosis of COVID-19 or have active respiratory illness symptoms?
   ☐ Yes ☐ No
2. Do you have known allergy and/or medical contraindication to CHG or povidone-iodine?
   ☐ Yes ☐ No
3. Do you have any medical and/or surgical reason(s) that would interfere with and/or prevent nasal swabs?
   ☐ Yes ☐ No
4. Are you a female who is either pregnant or suspects you are pregnant at this time?
   ☐ Yes ☐ No
5. In the last 30 days, have you used any treatments or interventions as part of any other COVID-19-related investigational trials (including a vaccine)?
   ☐ Yes ☐ No
6. Are you an essential worker who works in-person for some or all of your job duties?
   ☐ Yes ☐ No
7. Are you a healthcare worker?
   ☐ Yes ☐ No
8. Are you aged 18 or older?
   ☐ Yes ☐ No
9. Are you able to read and confirm consent?
   ☐ Yes ☐ No
10. Are you willing and able to perform the intervention and data collection procedures as described in this consent document?
    ☐ Yes ☐ No

What will happen in this study?

If you decide to participate in this research study, the researchers will first ask you questions about your demographics, work information, and general health information that may be relevant to analyses. The researchers will also ask you for a preferred mailing address to ship relevant study supplies. For three weeks of your participation in the study, the researchers will ask you to swab your nose with povidone iodine nasal swabs and rinse your mouth with chlorhexidine mouthwash. You will do these antisepsis procedures every day during the three week period.

A figure depicting the study design is below (Figure 1). During Phase 1 (weeks 1-3), you will be assigned either to the intervention group (oral and nasal antisepsis) or the control group (no oral or nasal antisepsis). After Phase 1 there is a washout period of two weeks (weeks 4-5). You will not do any antisepsis procedures during this washout period. In Phase 2 (weeks 6-8), after the washout period, your treatment group is switched (i.e. if you had intervention in Phase 1, you switch to control in Phase 2, and vice versa). Each participant will complete both parts of the study. 50% of participants will do Phase 1 first, and 50% of participants will do Phase 2 first. This will be random.

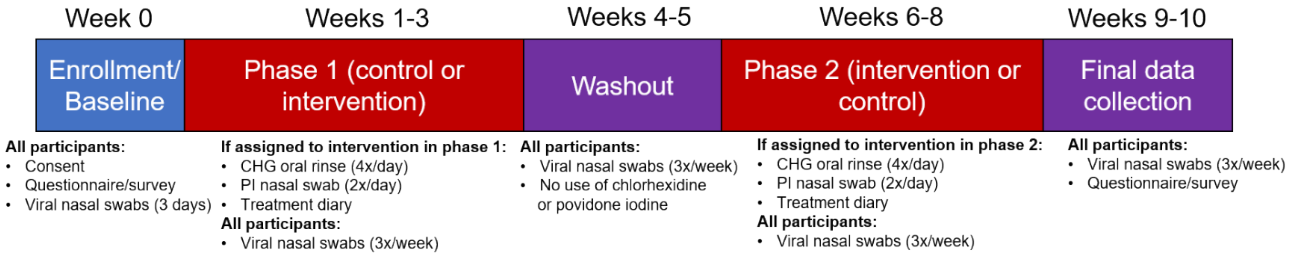

Figure 1. Overview of study activities and timeline for participants. Abbreviations: CHG = chlorhexidine gluconate; PI = povidone iodine.

For the nasal antisepsis, you will apply two povidone iodine-saturated swab sticks to each nostril, with slight pressure using a circular motion in the anterior nasal wall for at least 15 seconds. You will apply these nasal swabs twice per day approximately 12 hours apart. For the oral antisepsis, you will swish 15mL of CHG mouthwash for 30 seconds 4 times per day.

The researchers will ask you to collect nasal swabs three times per week for the 10-week study period. Before you begin Phase 1 – regardless of whether you are assigned to the intervention or control group – the study team will ask you to collect one nasal swab per day for three days in a row. You will use a single, sterile polyester swab to sample both nostrils. To collect nasal samples, you will insert the dry double-headed swab tips into the widest part (about 2 cm inside) of your right or left anterior nostril. You

will apply gentle pressure with a finger to the outside of the nose on the side being swabbed, then rotate the swab 4 times, for about 3 seconds. You will then use the same swab used to sample from the first nostril to swab the other nostril. These nasal swabs will be used to measure the presence of SARS-CoV-2 genetic material, which is from the virus that causes COVID-19. While this test measures the presence of this material, it is different from the test used to diagnose COVID-19 and so we are not able to diagnose you with COVID-19. You should continue to follow all of your employer's and medical provider's recommended health procedures for COVID-19 testing if you participate in this study.

The researchers will ask you to complete a survey describing your age, employment position, and some questions regarding your work, lifestyle, and relevant medical history. The researchers will also ask you to complete a treatment diary during the three week period that you are performing the antisepsis procedures. This diary will ask about if and when you were able to complete the antisepsis procedures. You will also be asked about any COVID-19 tests and results that you receive while participating in this research study. At the beginning and end of the study period, the researchers will also ask you to complete a brief survey about the feasibility and acceptability of the decolonization procedures. The survey asks questions regarding how you feel about measures taken to protect you from COVID-19 both before and during the study, how burdensome study decolonization it is, and how well you tolerated it. This is to help the research team understand how easy or difficult it may be to implement the study interventions if they appear to be effective. You may skip any question on the treatment diary or the surveys that you do not wish to answer. A study coordinator may contact you to check in on progress and answer any questions you may have. You may also reach out to the study team at any time during your participation.

For employees of UWHealth, the researchers will collect your COVID-19 infection information from UWHC Employee Health. If you do become sick for any reason and cannot care for patients, you will be withdrawn from the study. However, if your health situation resolves and you are able to go back to work and provide patient care, you can enroll again into the study if you are eligible.

Protected health information (PHI) used in this study
Protected health information, also called PHI, is information about your physical or mental health that includes your name or other information that can identify you, like your date of birth or medical record number. To do this study, we will use the following kinds of PHI:

- Shipping address for receiving study supplies
- Results of tests or procedures done as part of the study
- Things you tell the researchers about your health

- Employees of UW: information related to COVID-19 infection included in your Employee Health records, if you have or develop an active infection.

How long will I be in this study?
You will be part of the study for 10 weeks. Of that 10-week period, you would spend 3 weeks completing the antiseptic decolonization procedures. You would also collect the nasal swabs three times per week for the duration of the 10-week study period, as well as for the three days immediately prior to beginning Phase 1.

The researchers may take you out of the study, even if you want to continue, if
- your health changes
- you do not follow the study rules
- the study is stopped by the researchers

Do I have to be in the study? What if I say "yes" now and change my mind later?

No, you do not have to be in this study. Taking part in research is voluntary. This means that you decide if you want to be in the study. If you decide now to take part, you can choose to leave the study at any time.

If you decide to be in the study, the researchers will tell you about new information or changes in the study that may affect your willingness to continue in the study. Let the researchers know if you choose to leave the study.

If you decide not to take part in the study, or if you choose to leave the study, your choice will not affect your employment at the University of Wisconsin-Madison, any organizations affiliated with UW-Madison, or UW Health. If you receive health care from UW Health, if you decide not to take part in the study, or if you choose to leave the study, your choice will not affect your care through UW Health. No matter what decision you make, and even if your decision changes, there will be no penalty to you. You will not lose any legal rights.

Your authorization for researchers to use your protected health information (PHI) will does not have an end date. However:
- You can choose to take back your authorization for researchers to use your health information. You can do this at any time before or during your participation in the research.
- If you take back your authorization, information that was already collected may still be used and shared with others, but the researchers will no longer be able to collect NEW information about you.
- If you take back your authorization, you will not be able to take part in the research study.

- To take back your authorization, you will need to tell the researchers by writing to the Lead Researcher, Nasia Safdar at University of Wisconsin-Madison, Division of Infectious Disease, 5th Floor UW Medical Foundation Centennial Building, 1685 Highland Ave, Madison, WI, 53705.

What are my other choices if I do not take part in this study?

You do not have to be in this research study. If you decide not take part in the study, you will still have access to all other infection protection equipment and procedures (for example, personal protective equipment) as designated by your employer.

Will being in this study help me in any way?

Being in this study may provide additional protection against developing COVID-19. While the antisepsis procedures with povidone iodine and chlorhexidine may reduce the transmission of the SARS-CoV-2 virus, we cannot promise this will happen. Even if the study does not benefit you directly, your participation in this study may help other people in the future by helping us learn if povidone iodine and chlorhexidine are effective and feasible options to help reduce the transmission of viral respiratory infections.

This study is not a substitute for your regular medical care. You should continue to see your regular medical providers.

Will I receive the results of research tests?

The nasal swabs we are collecting are not able to diagnose COVID-19. Since they cannot be used to diagnose you or anyone else, we will not tell you or your doctors the results of these research tests. If you have symptoms of COVID-19, you should follow all of your employer's and/or medical provider's instructions for diagnostic testing.

What are the risks?

The risks of this study are low. The chlorhexidine oral rinse and povidone iodine nasal treatment are commonly used for infection prevention in the healthcare setting. However, you should not participate in this study if you have a medical reason (such as an allergy) to avoid any of the ingredients in chlorhexidine or povidone iodine.

Side effects of the povidone iodine treatment can include skin irritation or redness. Nasal swabs can cause minor nosebleeds, sneezing, and skin redness.

Side effects of oral CHG rinse include tooth and tongue discoloration/staining, increase in tartar formation, alteration in taste perception and an allergic reaction. Other potential adverse effects include oral irritation or inflammation (sores or cysts on the inside of the mouth, irritation of gums, redness, peeling skin, a white coating, hardening of the oral

mucosa, smooth patches on the tongue, and restricted range of motion of the tongue). Each side effect happened in less than 1/100 people.

There is a risk that your information could become known to someone not involved in this study, which might make you uncomfortable.

Will being in this study cost me anything?

There will be no cost to you for any of the study activities or procedures.

Will I be paid or receive anything for being in this study?

As a thank you for your efforts in participating in this study you will receive a $50 stipend at the completion of study participation.

What happens if I am injured or get sick because of this study?

If you are injured or get sick because of this study, medical care is available to you through UW Health, your local provider, or emergency services, as it is to all sick or injured people.

- If it is an emergency, call 911 right away or go to the emergency room.
- For non-emergency medical problems, contact your regular health care provider.
- Call the Lead Researcher, Nasia Safdar, at (608) 213-4075 to report your sickness or injury.

How will researchers keep my research information confidential?

We have strict rules to protect your personal information and protected health information (PHI). We will limit who has access to your name and other information that can identify you; all research data will be handled with the highest confidentiality and discretion by trained researchers who are approved to work on this study. We will also store this information securely. All samples you provide will have your name and all personal information removed. Only authorized study team members will be able to trace your samples and data back to you, and they will perform all work following UW's privacy policy. No study results that could identify you will be shared with others outside of the study.

However, we cannot promise complete confidentiality. Federal or state laws may permit or require us to show information to university or government officials responsible for monitoring this study. We may also have to tell appropriate authorities, such as child protective services or health care providers, if we learn during the study that you or others are at risk of harm (for example, due to child or elder abuse, or suicidal thoughts). Authorizing the research team to use your PHI means that we can release it to the people or groups listed below for the purposes described in this form. Once your health information is released outside UW-Madison or UW Health it may not be protected by privacy laws and might be shared with others. Also, with appropriate

institutional permissions and confidentiality protections, we might use information and biospecimens that we collect during this study for other research or share with other researchers without additional consent or authorization from you or your legally authorized representative.

Who at UW-Madison can use my information?

- Members of the research team
- Offices and committees responsible for the oversight of research

Who outside the UW-Madison may receive my information?

- The U.S. Food and Drug Administration (FDA)

Will information from this study go in my medical record?

- None of the information we collect for this study will go in your medical record. The researchers are not required to release health information to you if it is not part of your medical record.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

What if I have questions?

If you have questions about this research, please contact the Lead Researcher, Nasia Safdar at (608) 213-4075. If you have any questions about your rights as a research subject or have complaints about the research study or study team, contact UW Health Patient Relations at 608-263-8009. The Patient Relations Representatives work with research subjects to address concerns about research participation and assist in resolving problems.

Optional study activities

You will be asked to indicate below whether you consent to allow any leftover nasal swab samples collected for this study to be stored at UW-Madison to be used for future research in order to learn more about viruses. Your specimens would be labeled with a code, linked to information collected during this study, such as your medical history. However, any information that could identify you will be stored separately from your samples for purposes of the banking.

These samples and data will be kept indefinitely, meaning there are no plans to destroy them. You can decide if you want your sample to be used for future research or have them destroyed at the end of the study. Your decision can be changed at any time, even

after the study ends by notifying the study team. However, if you consent to future use and some of your nasal swabs have already been used for research purposes, the information from that research may still be used.

Samples may be shared with other researchers at other institutions outside UW-Madison with their consent. Each sample will be coded (labeled) only with a barcode and a unique tracking number to protect your confidentiality. Research using stored samples and data may be conducted by other institutions. Any samples provided to the receiving-institution will be coded. In no case will either individual personal identifiers or the key linking coded data to individuals be released to the other (receiving) institution. Please initial below indicating your preference. Your decision to allow us to store these samples is optional and does not affect your participation in the study. We will only store leftover samples and no additional nasal swabs will be collected.

☐ By checking this box I agree to the sample banking component as described above.

☐ By checking this box I do NOT agree to the sample banking component as described above and wish for my samples to be destroyed at the end of study.

Agreement to participate in the research study

You do not have to sign this form. If you refuse to sign, however, you cannot take part in this research study.

If you sign the line below, it means that:

- You have read this consent and authorization form.
- You have had a chance to ask questions about the research study, and the researchers have answered your questions.
- You want to be in this study.
- You give authorization for your protected health information to be used and shared as described in this form.

_____

Printed Name of Research Participant

_____

Signature of Research Participant Date

****Please retain a copy of this signed document for your records and future reference****