THE QUEEN'S MEDICAL CENTER
HONOLULU, HAWAIl

INFORMED CONSENT TO TAKE PART IN A CLINICAL RESEARCH STUDY

Title of Study: Vapocoolant Application for Pain Reduction during Office-based Gynecologic Procedures: a Randomized Controlled Trial (VAPOR)

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Sponsor: Lakshmi Devi and Devraj Sharma Endowment

Summary of Key Information

- You are being asked to take part in a research study because you are having a procedure that includes a paracervical block, an injection that can reduce pain. This consent form has important information to help you decide if you want to join the study or not. Your decision to be a part of the study is voluntary.
- The purpose of this study is to learn more about vapocoolant spray, a device that may be helpful in decreasing pain with injections. We are hoping to find out that this device makes the injection you receive today less painful.
- Num Vapocoolant is used on skin to decrease pain with injections. As we are using it in the vagina, this is an off label use.
- Taking part in this study will not add any extra visits to your care.
- This study involves receiving either the vapocoolant spray or a placebo (no active drug) during your procedure.
- The risks of the Num vapocoolant spray include second and third degrees bums, cryogenic injury, failure of the canister, bruising, blistering, bleeding, pain, blister, cryogenic burn, infection, discharge.
- We cannot promise any benefits from taking part in this study. However, it may be less painful for you, and if found to be effective, it may help make this procedure for future patients who undergo this procedure.
- You will not have to pay for the vapocoolant spray or placebo. Even if you decide to take part in this study now, you can decide to stop participating at any time.
- Safeguards are in place to protect your privacy.
- The information you provide during the study will not be labeled with your name or other personal information that could identify you.

End of Key Information Summary

Informed Consent

You are being asked to take part in a research study because you are having a procedure that includes a paracervical block, an injection that can reduce pain. This research study investigates whether vapocoolant spray reduces pain during this procedure.

Before you decide whether or not to take part in this study, you must understand the purpose, how it may help, any risks, and what you have to do. This process is called informed consent. The researcher(s)will talk with you about the study and the informed consent form. The consent also gives you information about what health information will be collected as part of the research study and how that information will be used or disclosed. Once you understand the study, and if you agree to take part, you will be asked to sign this consent form. If you sign this form you are agreeing to take part in this study and to allow the use and disclosure of your medical records and health information collected in connection with your part in this study. You will be given a **signed** copy to keep. If you do not sign this consent form, you will continue to receive care, but not as part of this study.

Before you learn about the study, it is important that you know the following:

- Taking part in this study is of your own free will.

- You may decide not to take part in the study or stop being in the study at any time without it making any difference to your care now or in the future, or to any benefits that you are allowed.
- If the study changes in any way which could make a difference to your taking part, you will be told about the changes and may be asked to sign a new consent form.

PURPOSE OF THE STUDY

Gynecologic office procedures are common and painful. For office-based procedures, providers routinely use a lidocaine injection into the cervix, known as a paracervical block, to decrease pain. However, the paracervical block itself is painful. Vapocoolant spray has been found in other specialties to decrease pain with injections, but it has not yet been investigated in gynecologic procedures. Vapocoolant spray is easy to use, rapidly acting, inexpensive (approximately 5 dollars for a single use vial) and readily available.

In this study, we plan to use Num vapocoolant spray on the cervix before the paracervical block to see if this decreases pain with the injection. Therefore, we are approaching any patient who has decided to have a procedure with a paracervical block that also meets our inclusion criteria.

PROCEDURES

Screening

You are being asked to take part in this study since you are already scheduled for a gynecological procedure (for example, abortion that is less than 13weeks 6 days, IUD insertion, laminaria placement) that requires a paracervical block. You have already received standard counseling for that procedure and completed a separate informed consent for that procedure.

If you agree to take part in this study, you will need to sign this informed consent.

Study Treatment

After receiving the usual pre-procedure medications (such as ibuprofen 600 mg), the usual wait time is about 10 minutes. During this wait time, a research coordinator will ask 13 questions about you and your history.

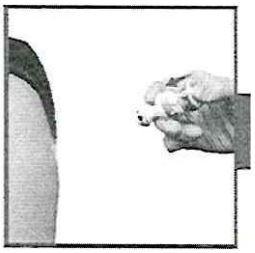
You will receive standard of care + a spray after speculum placement. The spray will be either the Num vapocoolant spray or placebo Nature's Tears. All other aspects of the procedure will remain the same.

You will be randomized (chosen by chance, like a coin toss) to receive a one-time dose of either Num vapocoolant spray or a placebo Nature's Tears spray during the IO-minute procedure. You have a 50 percent chance of receiving this vapocoolant spray. A study coordinator will ask you about your pain throughout the procedure. After the procedure, your vagina and cervix will be checked as usual; at the same time, the doctor will also evaluate for any side effects of the

vapocoolant/placebo. Otherwise, the paracervical block will be performed in the same way it is always performed.

There is no additional time added to the procedure by being in the study.

The Num Vapocoolant spray works by causing a cold sensation that numbs the nerves. The cold decreases pain immediately after it is sprayed. The Num vapocoolant spray is a device and each bottle/container is one time use. Each patient will receive one spray. The physician will spray for about 4-6 seconds, the numbing effect lasts 1 minute.



Follow Up Visits:

One or two days after the procedure, one of the study doctors will text and/or call you to see if you have any concerns or symptoms that would require an exam. If none is needed, then your time in the study is done.

Length of Time in the Study
You will be in the study from when your procedures start to the follow-up visit. The procedure is the same length of time as if you decided to not do the study.

Stopping Your Part in the Study (Withdrawal or Early Termination)
You can decide to stop taking part in the study at any time without any consequences.

Risks
The risks of vapocoolant spray include irritation, thermal burn, bruising, blistering, thawing process may be painful, and delayed healing

Immediately after the procedure (which usually lasts about 10 minutes), we will do a full evaluation of your cervix and vagina to look for these possible side effects. Allergic reactions generally occur rapidly. As the vapocoolant is applied at the beginning of the 10-minute procedure, we will assess at the end of the procedure for any side effects of allergic reaction symptoms (hives, bumps, irritation).

We will also text or call you 1-2 days after procedure to evaluate if you have any concerning symptoms. If you do, we will schedule for an appointment as soon as possible to evaluate you in person.

Benefits

If you participate in this study, you may have decreased pain with the procedure, but no guarantee can be made and it is possible that you have the same amount of pain. If this medication is found to be effective, routine use of it could help other people having this procedure have decreased pain.

Other treatment

You may choose to not take part in this study without it making a difference in the care that you get now or in the future. You do not need to be in this study to receive the procedure with the paracervical block that you have consented to.

Confidentiality

Federal Privacy Regulations provide safeguards for privacy, security, and authorized access to health information. The confidentiality of all study-related records will be kept according to all applicable laws. Information gained during this study and information known about you will be confidential (private) to the extent permitted by state and federal law. The results of this research may be presented at meetings or in publications; however, your identity will not be disclosed.

Your information or samples that are collected as part of this research will not be used or given for future research studies, even if all of your identifiers are removed.

HIPAA AUTHORIZATION TO USE AND DISCLOSE YOUR PERSONAL HEALTH INFORMATION

We understand that information about you and your health is personal, and we are committed to protecting the privacy of that information. Because of this commitment, we must obtain your special authorization before we may use or disclose your protected health information (PHI) for the research purposes described below. If you sign this authorization, your entire research record and any medical records may be used and disclosed as described below for the purposes described in this form. The information collected about your health will be entered into a computer database and kept indefinitely.

The purpose of this section is to make sure that you are properly told of how your PHI will be used or disclosed. Please read the information below carefully before signing this form.

Use and Disclosure (Release) of your Health Information/HIPAA Authorization

By signing this form, you are authorizing the collection, use and release of your personal health information in medical records and diagnostic imaging and any health information gathered about you as part of this study. Your information will only be used/disclosed as described in this consent form and as permitted by state and federal laws. Your personal health information is health information about you that could be used to identify you. This information may include

information about AIDS or HIV infection, treatment for alcohol and/or drug abuse, or mental health or psychiatric services.

The purposes of releasing your protected health information are to collect the data needed to complete the research, to properly monitor (watch) how the study is done, and to answer research questions related to this study.

There is no expiration date to this authorization.

Who may receive, use or release information:
Your medical records and any health information related to this study may be used or released in connection with this research study to the following:

- Dr. Rault, Dr. Raidoo, Dr. Kaneshiro, Dr. Soon, Dr. Natavio, Dr. Chen, Dr. Manayan and their research staff for the purposes of conducting this research study.
- The Research and Institutional Review Committee of QMC and staff members of the Research Regulatory Office for purposes of overseeing the research study and making sure that your ethical rights are being protected.
- Providers and other healthcare staff of QMC involved in your care.

Who may receive the information by the above groups:
The individuals or groups named above may release your medical records, this consent form and the information about you created by this study to:

- Federal, state and local agencies having oversight over this research, such as The Office for Human Research Protections in the U.S. Department of Health and Human Services, Food and Drug Administration,
- Representatives directed by QMC Research Department for audits to make sure studies are done as required.
- Staff in billing-related departments and insurance companies for billing purposes

There is a possibility that your information may be released again by the governmental agencies described above and no longer covered by federal privacy rules.

Right to Withdraw or Stop Taking Part in the Study
You may refuse to sign this authorization. If you refuse to sign the authorization, you will not be able to take part in this study. If you choose not to be in the study, or choose to withdraw from the study, or if you refuse to sign the authorization, it will not make a difference in your usual treatment, or your payment, and it will not change your eligibility for any health plan or health plan benefits that you are allowed.

If you decide to end your taking part in the study or you are removed from the study by the researcher (study doctor), you may revoke (take away) your authorization. In order to take away this authorization, you must send a letter/notice to the researcher in charge of this study. Send the written notice to the researcher to the address listed on the original consent form.
If you take away your authorization, your part in the study will end and the study staff will stop collecting medical information from you and about you. The researchers and sponsor will continue to use information that has already been collected, but no new information about you

will be collected unless the information is about an adverse event (a bad side effect) related to the study or to keep the scientific integrity of the study. If an adverse event happens, we may need to review your entire medical record.

Access to Your Information

You may see the information in your medical record; however, the records and information related only to the study that are kept separately will not be available to you until the study is finished. If you wish to review your study records after the completion of the study, you should request this from the study doctor.

END OF HIPAA AUTHORIZATION SECTION

Payments To You For Taking Part In The Study

You will receive a $50 gift card after the procedure through the University of Hawaii (UH).

If you receive payments for being part of this research study, UH is required to collect your name, address, and social security number through an Internal Revenue Service (IRS) Form W-9. If you receive more than $600 per year for taking part in one or more research studies, UH will send you an IRS Form 1099. You may be required to pay taxes on that money. This does not include any payments you receive to pay you back for expenses like parking fees.

Costs

The vapocoolant spray and placebo will be provided by the Society of Family Planning through the University of Hawaii at no cost to you.

For costs of medical services for care you would receive even if you were not in this research study:

- You and/or your insurance company will be responsible for the cost of routine medications, tests and procedures that you would receive even if you were not in this research.
- You and/or your insurance company will be billed for the costs of these routine tests and procedures in the usual manner.
- You will be responsible for any co-payments, co-insurance and deductibles that are standard for your insurance coverage.
- You will be responsible for any charges not reimbursed by your insurance company.
- Some insurance companies will not pay for routine costs for people taking part in research studies. Before deciding to be in this research you should check with your insurance company to find out what they will pay for.

If you have any questions about costs and insurance, ask the research study doctor or a member of the research team.

Financial Disclosure

The Society of Family Planning will pay for certain materials and supplies for carrying out this study. Dr. Rault and Dr. Raidoo are employees of The Queen's Medical Center and will not

financially benefit directly from being the principal investigators for this study or for carrying out this study on behalf of The Queen's Medical Center.

Treatment and Compensation for Injury

If you have an injury or illness (get sick) as a result of being in this study, immediate emergency medical care and treatment which may be needed will be provided. You or your insurance will be responsible for costs associated with this emergency care. The sponsor of the study, the study doctor, and The Queen's Medical Center do not have any funding (money) to pay for treating the injury or illness. Your insurance company may not pay for some (or all) of the treatment of the injury or illness as a result of being in this study. If your medical insurance does not pay for these medical costs, you alone will be responsible for payment. There is no way of knowing what the costs will be. You should talk about the kind of insurance coverage you have with your doctor and insurance company before you decide to take part in this study. You can have financial counseling to go over your insurance coverage.

The sponsor, The Queen' s Medical Center and the study researchers have not set aside any other kind of compensation (payment) for lost wages or other damages or losses resulting from any injury that you may get from taking part in this study.

Removal From the Study

You take part in this study of your own free will.
You can be removed from the study without your consent if the study doctor believes it is not in your best interest to continue.

NEW FINDINGS

You will be told of any important new information learned during the study that may change your willingness to continue in this study. You may be asked to sign a new updated consent if this happens.

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

Who to Contact

If you feel that you have been injured as a result of taking part in this study, if you have any questions about your treatment, your rights as a volunteer or any other matter relating to this study, you may call Dr. Rault at 808-375-3785.

If you cannot get satisfactory answers to your questions or you have comments or complaints about your treatment in this study, you may contact:

Research & Institutional Review Committee
The Queen's Medical Center
1301 Punchbowl Street
Honolulu, HI 96813 Phone: (808) 691-4512

RA- 2023-046

AGREEMENT TO TAKE PART AND CERTIFICATION **and** ***AUTHORIZATION OF PROTECTED HEALTH INFORMATION -***

I have read and understand the description of this study such as the purpose and nature of this study, its expected length, the procedures to be done, reasonably known risks and discomforts, benefits to expect, other treatments I may have, release of my medical records, payment and medical treatment for injury, and removal without my consent for this research study.

I am taking part in this study of my own free will. I may withdraw (stop taking part) and/or withdraw my authorization for use and release of protected health information at any time after signing this consent form without it making a difference to my care now or in the future or any loss of benefits that I am allowed. My consent does not take away my legal rights in case of carelessness or negligence of anyone connected with this study. My signature means that I have read the information above or that it has been read to me, my questions have been satisfactorily answered, and at any time I have other questions, I can contact the researcher listed on the first page.

Specially Protected Health Information

I agree to the release of the following information should it be contained in my medical records: alcohol and/or drug abuse treatment, if it exists in my medical record.

cc: ***Signed copy*** of consent/authorization form to patient

Subject's Name (Print)	Subject's Signature	Date/ Time
Witness' Name (Print) (Witnessing Signature Only)	Witness' Signature **********	Date / Time

I have explained this research to the above subject. In my judgment the subject is voluntarily and knowingly giving informed consent and has the legal capacity to give informed consent to take part in this research study.

Investigator' s Name (Print) (Individual obtaining Subject' s consent)	Investigator's Signature	Date/ Time

Investigator:

- Fax a copy of this signed page to the Research Regulatory Office at 691-7897 within 24 hours of signing.
- Document in Medical Record: study name, sponsor, and sponsor-assigned protocol number, consenting
- Scan/copy signed consent for Medical Record