Isopropyl Alcohol as Anti-Emetic Therapy in the Emergency Department: Study Protocol for a Multi-Center Randomized Controlled Trial

Alexandra Hamelin[1], Ali Shahbaz Syed[1], Venkatesh Thiruganasambandamoorthy[1,2]

[1]Department of Emergency Medicine, University of Ottawa, Ottawa, ON, Canada
[2]The Ottawa Hospital Research Institute, Ottawa, ON, Canada

Date Submitted: November 10, 2021
Date Accepted: March 29, 2022
Date Published: July 19, 2024

DOI: https://doi.org//10.18192/uojm.v13i1.6100

Keywords: *emergency department, isopropyl alcohol, inhalation, nausea, vomiting*

ABSTRACT

Background: Nausea and vomiting are common and distressing presenting complaint in Emergency Departments (EDs). There is no definite evidence to support the superiority of any anti-emetic therapy over another or over placebo. Identification of an effective anti-emetic therapy in the ED setting with minimal side effects would be of great benefit. Isopropyl alcohol inhalation has been reported to be an effective treatment for post-operative nausea and vomiting, with no reported adverse events. This manuscript presents the protocol for a study aiming to determine if nasally inhaled isopropyl alcohol swabs are effective in alleviating nausea and/or vomiting in patients presenting to the ED with a chief complaint of nausea and/or vomiting.

Methods: We will conduct a randomized, controlled, multicenter trial with three subject arms: 1) nasally inhaled isopropyl alcohol swabs every 10 minutes for a total of one hour, 2) nasally inhaled isopropyl alcohol swabs every 20 minutes for a total of one hour, or 3) no intervention. 135 participants ≥18 years old and presenting to the ED with a chief complaint of nausea and/or vomiting with a level of 3 or greater on a verbal numeric rating scale (NRS) will be recruited for a duration of two hours. The primary outcome measure is the mean reduction in nausea scores, comparing the pre-intervention score to the lowest post-intervention nausea score. The secondary outcome measures will be participant satisfaction scores using a verbal NRS, receipt of any rescue anti-emetic medications, a number of vomiting episodes during ED stay, ED length of stay, and participant disposition (admission or discharge home).

Conclusion: This study will determine the efficacy of inhaled isopropyl alcohol swabs in treating patients with nausea and vomiting in the emergency department. By determining the optimal dosing frequency, this has the potential to guide future triage protocols incorporating this therapy to provide earlier symptomatic relief to patients while improving patient satisfaction and efficiently using in-patient resources.

RÉSUMÉ

Contexte: Les nausées et les vomissements sont des symptômes fréquents et pénibles dans les services d'urgence. Il n'existe pas de preuves formelles de la supériorité d'un traitement antiémétique par rapport à un autre ou par rapport à un placebo. L'identification d'une thérapie antiémétique efficace dans le contexte des urgences, avec des effets secondaires minimes, serait d'une grande utilité. L'inhalation d'alcool isopropylique s'est révélée être un traitement efficace contre les nausées et vomissements postopératoires, sans effets indésirables signalés. Ce manuscrit présente le protocole d'une étude visant à déterminer si les tampons d'alcool isopropylique inhalés par voie nasale sont efficaces pour soulager les nausées et/ou les vomissements chez les patients se présentant aux urgences avec une plainte principale de nausées et/ou de vomissements.

Méthodes: Nous mènerons un essai randomisé, contrôlé, multicentrique avec trois groupes de sujets: 1) inhalation nasale de tampons d'alcool isopropylique toutes les 10 minutes pendant une heure au total, 2) inhalation nasale de tampons d'alcool isopropylique toutes les 20 minutes pendant une heure au total, ou 3) pas d'intervention. 135 participants âgés de ≥18 ans et se présentant aux urgences avec une plainte principale de nausées et/ou de vomissements avec un niveau de 3 ou plus sur une échelle d'évaluation numérique verbale (ÉÉN) seront recrutés pour une durée de deux heures. Le principal critère de jugement est la réduction moyenne des scores de nausées, en comparant le score avant l'intervention au score le plus bas après l'intervention. Les résultats secondaires seront les scores de satisfaction des participants à l'aide d'une échelle verbale ÉÉN, la réception de médicaments antiémétiques de secours, le nombre d'épisodes de vomissements pendant le séjour aux urgences, la durée du séjour aux urgences et la disposition des participants (admission ou sortie à domicile).

Conclusion: Cette étude déterminera l'efficacité des tampons d'alcool isopropylique inhalés dans le traitement des patients souffrant de nausées et de vomissements au service des urgences. En déterminant la fréquence de dosage optimale, elle pourrait guider les futurs protocoles de triage intégrant cette thérapie afin de soulager plus rapidement les symptômes des patients tout en améliorant leur satisfaction et en utilisant efficacement les ressources hospitalières.

INTRODUCTION

Nausea and vomiting are common and distressing presenting complaints in Canadian Emergency Departments (EDs). The frequently used anti-emetic medications used to treat nausea and vomiting in the ED, including ondansetron, metoclopramide and dimenhydrinate, have proven efficacious in the treatment of specific patient populations (i.e. chemotherapy patients and post-operative nausea and vomiting).[1,2] However, in the ED setting, there is no definite evidence to support the superiority of any one medication over another or the superiority of any medication over a placebo.[3] Furthermore, these medications have been associated with adverse effects, including a feeling of internal restlessness, sedation, and life-threatening heart rhythm abnormalities.[3,4] These medications also have the potential to interact with a patient's own medications, limiting their use before the patient is assessed by the treating physician.

Emerging evidence exists supporting the use of nasally inhaled isopropyl alcohol swabs as anti-emetic therapy. While the mechanism of action of isopropyl alcohol's anti-emetic effect remains unclear, theories exist that this effect may be related to olfactory distraction. Multiple studies report isopropyl alcohol inhalation as an effective treatment for post-operative nausea and vomiting when compared to placebo, with no reported adverse events.[5] This relatively inexpensive substance is widely available in most health care settings in the form of swabs used in the routine course of delivering care as an antiseptic skin cleanser. Two previous studies in the United States have evaluated the use of inhaled isopropyl alcohol swabs in alleviating nausea and vomiting in the ED setting.[6,7] A 2016 study by Beadle et al. demonstrated superior nausea relief using inhaled isopropyl alcohol swabs compared to an inhaled placebo. Moreover, a 2018 study by April et al. demonstrated that isopropyl alcohol swabs, with or without oral ondansetron, provided greater nausea relief than oral ondansetron alone.[6,7] These two studies in the ED setting also did not report any adverse events.[6,7]

The 2016 study by Beadle et al. has several important limitations. This was a single-center military hospital study, which only measured nausea scores 10 minutes after isopropyl alcohol swab inhalation and lacked other important outcomes, such as the number of vomiting episodes, use of rescue anti-emetics, ED length of stay and admission rates. The 2018 study by April et. al. also has limitations. Mainly, alcohol swabs were used as often as required by participants, and the dosing frequency of inhalations was not measured. They also excluded patients who had a peripheral IV catheter inserted on arrival, which may suggest that patients with more severe symptoms of nausea and vomiting requiring IV anti-emetics were excluded.

Identification of effective anti-emetic therapy in the ED setting with minimal side effects would be of great benefit to the ED provider. Our goal is to add to the current body of evidence on the use of isopropyl alcohol in alleviating nausea and vomiting in the ED setting, particularly by determining which dosing frequency of isopropyl alcohol inhalation yields the most effective nausea relief by randomizing patients to different inhalation frequencies. This may help to guide future triage protocols enabling isopropyl alcohol inhalation before provider evaluation to improve treatment of nausea and patient satisfaction. In the current state of ED crowding, the ability to adequately control a patient's symptoms at triage may help decrease a patient's length of stay as well as the number of patients requiring beds. In addition, from a cost-savings perspective, alcohol swabs are a relatively inexpensive therapy as compared to many commonly administered anti-emetics.

Given that there is no universally accepted standard of care in treating nausea and vomiting in the emergency department setting, there will be no treatment group for comparison.

The primary objective of this study is to determine if nasally inhaled isopropyl alcohol swabs are effective in alleviating nausea and/or vomiting in patients presenting to the ED with a chief complaint of nausea and/or vomiting. The secondary objectives are to determine the optimal dosing frequency of nasally inhaled isopropyl alcohol swabs as either every 10 minutes or every 20 minutes in patients presenting to the ED with a chief complaint of nausea and/or vomiting. Other secondary objectives are to determine the effect of nasally inhaled isopropyl alcohol swabs on:

- Patient satisfaction
- Use of rescue anti-emetics
- Number of vomiting episodes during ED stay
- Patient's ED length of stay
- Patient's disposition either discharged from or admitted to hospital

METHODS

Study Design and Population

This study is designed as a randomized, controlled, multicenter trial. Subjects will be recruited in two urban, tertiary EDs in [blinded]. In each center, there are approximately 2000 patients presenting to the emergency department with a chief complaint of nausea and/or vomiting per year.

The inclusion criteria will be subjects who are over 18 years old and present to the ED with a chief complaint of nausea and/or vomiting with a level of 3 or greater on a verbal numeric rating scale ranging from 1-to-10. The exclusion criteria will be: subjects unable to breathe through their nares (i.e. rhinitis), pregnant, already received an anti-emetic within the past 24 hours (including while in ED triage), have chronic nausea (> 1 month), have a known allergy to isopropyl alcohol, who are nasally sensitive to inhaled chemical products or have an altered mental status or underlying cognitive impairment.

Patients who meet all inclusion criteria and none of the exclusion criteria will be offered the opportunity to participate in the study and provided with all the relevant information verbally and in writing. A convenience sample of potential study subjects will be identified by the research team during periods when available to enroll subjects. Participants will be recruited in the ED by the research team while in the waiting room or shortly after arrival to their assigned ED room, before the arrival of their treating physician and before any treatment is provided. The research team will speak with the emergency care team (i.e. nurses or physicians), who will obtain permission from the patient for the research team to approach the patient regarding the study before any anti-emetics are administered to the patient. There will be no financial compensation for patient participation in the trial.

All patients who give consent for participation and who fulfil the inclusion criteria will be randomized. The details regarding participant consent forms are outlined in Appendix 1. The research team will be responsible for obtaining written consent, enrolling patients and generating the allocation sequence.

The Ottawa Health Science Network Research Ethics Board (OHSN-REB) approved the protocol. A Natural Health Product Clinical Trial Application will be required by Health Canada prior to initiation of the study.

Trial Registration

ClinicalTrials.gov: NCT04464915

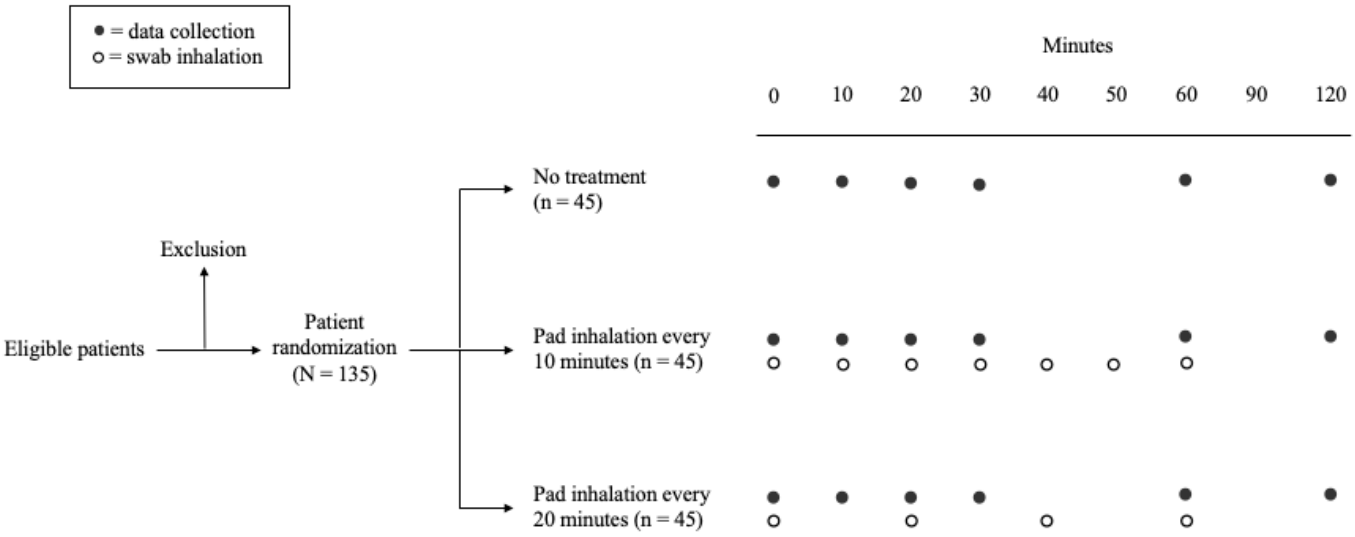

Figure 1. Flow diagram of study with identification of eligible patients and randomization to treatment arms, with timeline demonstrating data collection and swab inhalation time points.

Randomization

Participants will be randomly assigned to one of three treatment arms with a 1:1:1 allocation as per a computer-generated randomization schedule using permuted blocks of 6: 1) nasally inhaled isopropyl alcohol swabs every 10 minutes for a total of one hour; 2) nasally inhaled isopropyl alcohol swabs every 20 minutes for a total of one hour and 3) no intervention (Figure 1).

Allocation concealment will be ensured, as the service will not release the randomization code until the patient has been recruited into the trial. The research team will be responsible for generating the allocation sequence. Due to the nature of the intervention, neither participants nor research staff can be blinded to allocation. Given that blinding the scent of isopropyl alcohol would be challenging, there will be a no-treatment arm rather than a placebo group. Data analysts will, however, be blinded.

Retention

Given this relatively short study duration of two hours with frequent follow-up from the research team to obtain nausea scores, it is anticipated that this study will have a high level of participant retention which will the maximize completeness of data collection. Participants who voluntarily withdraw early from the study will be asked for permission to use their data. The participant will be asked if they wish to withdraw from the study intervention, however, permit data obtained to date to be included in the analysis, or withdraw from study the intervention and indicate that the data collected to date cannot be used in the final analysis.

Interventions

The intervention is Isopropyl alcohol swabs. Swabs will be administered by instructing patients to take one deep inhalation of a swab held 1-2cm below the nares. Intervals of administration will be either every 10 minutes or every 20 minutes for a total of one hour depending on the randomization arm. New swabs will be provided in a manufactured, sealed pouch as distributed by the manufacturer to the patient for each inhalation.

The active study duration will be two hours for each patient while in the ED from the time of randomization until the collection of nausea scores are completed after a total of two hours. There will be no further follow-up. The assigned study intervention may need to be discontinued by trial investigators if there are any adverse events, such as allergic reactions.

Patient compliance will be monitored by the research team administering the isopropyl alcohol swabs. The research team will hand one packaged swab at a time to the subject and observe for one full, adequate inhalation at the designated interval of every 10 minutes or every 20 minutes to ensure adequate compliance.

Patients who have used an anti-emetic in the past 24 hours will be excluded from the study. However, there will be no restrictions on the use of concomitant medications during the trial. Participants should continue to take medications for other conditions as normal. Any additional medications or treatments will be permitted by the treating physician during the trial, including any rescue anti-emetics.

Outcome Measures

The primary outcome reflecting the efficacy of the study intervention is the mean reduction in nausea scores comparing pre-intervention scores to the lowest post-intervention scores measured throughout the two hours of intervention, or the last nausea score before a rescue anti-emetic is administered by the treating physician.

The intervention will be determined to be effective if there is a reduction by 3 or more points on a self-reported 10-point verbal numeric scale ranging from 1-10, labelled "no nausea" at the left end (1) and "worst nausea imaginable" at the right end (10). This value was chosen based on values from previous studies using similar nausea scores.[6,7]

The verbal numeric rating scale is highly reliable among adult patients in the ED with nausea and/or vomiting and correlates highly with the visual analogue scale.[8] It has been shown to reliably differentiate between initial severity categories, change in severity, and patient satisfaction categories.[8] The numeric rating scale was chosen because of its practical use in the ED.

The secondary outcomes reflecting the efficacy of the study intervention are participant satisfaction scores, the receipt of any rescue anti-emetic medications, a number of vomiting episodes during ED stay (as defined by forceful expulsion of gastric content excluding non-productive retching or drooling), ED length of stay, and patient disposition (discharge from or admission to hospital). Satisfaction scores will be measured using a self-reported 5-point verbal numeric scale ranging from 1-5, labeled "very unsatisfied" at the left end (1) and "very satisfied" at the right end (5).

Sample Size

The goal is to estimate the efficacy of nasally inhaled isopropyl alcohol in alleviating nausea and/or vomiting in study subjects by measuring the reduction in patient-reported nausea scores by comparing pre-intervention scores to the lowest post-intervention scores. The minimally clinically significant difference is assumed to be 3 points on a self-reported 10-point verbal numeric scale ranging from 1-to 10. For $\alpha=0.025$ and $\beta=0.80$ using a t-test and a standard deviation of 3 points, the sample size required is 45 per participant's arm (135 participants total).

Data Collection

Primary outcome: Nausea scores will be measured at baseline before the intervention, 10 minutes after initiating the intervention, 20 minutes after initiating the intervention, 30 minutes after initiating the intervention, and then every 30 minutes for a total of two hours throughout the subject's ED visit.

Secondary Outcomes: Subject satisfaction scores will be measured either after two hours or when the final nausea score is obtained before a rescue anti-emetic is administered by the treating physician.

The receipt of any additional anti-emetic therapy will be documented, including medication, dosing and frequency. The number of vomiting episodes since the preceding data collection period will be documented. The participant's ED length of stay in minutes will be documented. The participant's disposition from the ED will be documented, as either discharged home or admitted to the hospital.

Exploratory Outcomes: The study will collect demographic information from the patient, including age, sex, tobacco use, alcohol use, illicit drug use, and medical comorbidities. Other relevant clinical information will be obtained, including duration of nausea and/or vomiting, presence of any additional symptoms, investigations and/or interventions completed by the ED physician, and final diagnosis at the time of ED disposition.

Statistical Analysis

The primary outcome, i.e., the mean reduction in nausea scores, will be analyzed using repeated measures linear regression analysis. The study arm, time and study arm by

time will be included as fixed covariates, and the correlation in repeated measures on the same subject over time will be modeled using a suitable covariance structure. Least square mean differences, together with 95% Confidence Intervals, will be used to express the treatment effect, comparing each of the intervention arms to the control arm. The statistical significance of each pairwise comparison will be judged at the 2.5% level to maintain the overall level at 5%. A similar approach will be used for ED lengths of stay (with transformation to improve normality if necessary). The number of vomiting episodes and receipt of antiemetic drugs will be analyzed using Poisson or logistic regression as appropriate. Participant baseline characteristics will be summarized with descriptive statistics with 95% confidence intervals.

All analyses will be with the intention to treat, considering all patients as randomized regardless of whether they received the randomized treatment. Dropouts (essentially, participants who withdraw consent for continued follow-up) will be included in the analysis by modern imputation methods for missing data. After the imputations are completed, all of the data (complete and imputed) will be combined, and the analysis performed.

CONCLUSION

Nausea and vomiting are common and distressing complaints in patients presenting to Canadian emergency departments. Identification of effective anti-emetic therapy in the ED setting with minimal side effects would be of great benefit to the ED provider. The use of inhaled isopropyl alcohol swabs has been proven to be efficacious in post-operative nausea and vomiting, and two recent ED studies have shown promising results in treating nausea and vomiting, with no reported adverse effects. This study will determine the efficacy of inhaled isopropyl alcohol swabs by determining the optimal dosing frequency that achieves adequate anti-emetic action, potentially guiding future triage protocols to incorporate this therapy. We strongly suspect that once this study is performed, it will be useful for ED physicians in treating nausea and vomiting in the ED.

REFERENCES

1. Hesketh PJ, Kris MG, Basch E, et al. Antiemetics: American society of clinical oncology clinical practice guideline update. J Clin Oncol. 2017;35(28):3240-3261.
2. Gan TJ, Diemunsch P, Habib AS, et al. Consensus guidelines for the management of postoperative nausea and vomiting. Anesth Analg. 2014;118(1):85-113.
3. Furyk J, Meek R, Egerton-Warburton D. Drugs for the treatment of nausea and vomiting in adults in the emergency department setting. Cochrane DB Syst Rev. 2015;(9):CD010106.
4. Patanwala AE, Amini R, Hays DP et al. Antiemetic therapy for nausea and vomiting in the emergency department. Journal Emerg Med. 2010;39(3):330-336.
5. Hines S, Steels E, Chang A, et al. Aromatherapy for treatment of postoperative nausea and vomiting. Cochrane DB Syst Rev. 2012;18(4):CD007598.
6. Beadle K, Helbling A, Love S, et al. Isopropyl alcohol nasal inhalation for nausea in the emergency department: A randomized controlled trial. Ann Emerg Med. 2016;68(1):1-9.
7. April M, Oliver J, Davis W, et al. Aromatherapy versus oral ondansetron for antiemetic therapy among adult emergency department patients: A randomized controlled trial. Ann Emerg Med. 2018;72(2):184-193.
8. Meek R, Egerton-Warburton D, Mee M, et al. Measurement and monitorings of nausea severity in emergency department patients: A comparison of scales and exploration of treatment efficacy outcome measures. Acad Emerg Med. 2015;22(6):685-693.

APPENDIX 1 - INFORMED CONSENT MATERIALS

Main Informed Consent Form for Participation in a Research Study

Study Title: Isopropyl Alcohol Inhalation as Anti-Emetic Therapy in the Emergency Department

OHSN-REB Number: [Blinded]

Study Doctor: [Blinded]

Introduction
You are being invited to participate in a clinical trial/study (a type of study that involves research). You are invited to participate in this trial/study because you presented to the emergency department with nausea and/or vomiting. This consent form provides you with information to help you make an informed choice. Please read this document carefully and ask any questions you may have. All your questions should be answered to your satisfaction before you decide whether to participate in this research study.

Please take your time in making your decision. You may find it helpful to discuss it with your friends and family.

Taking part in this study is voluntary. You have the option to not participate at all or you may choose to leave the study at any time. Whatever you choose, it will not affect the usual medical care that you receive outside the study.

Is there a conflict of interest?
There are no conflicts of interest to declare related to this study.

What is the background information for this study?
Nausea and vomiting is a common presenting complaint in Canadian emergency departments. Nausea medications are commonly used to help relieve these symptoms, however not one has been proven to be more effective than the other, and many are associated with side effects. Inhalation of alcohol swabs has been shown to be an effective therapy in relieving nausea and vomiting after surgery. This relatively inexpensive substance is widely available with no known side effects, which would be of great benefit in the emergency department in treating nausea.

Why is this study being done?
The purpose of this study is to determine if alcohol swabs are effective in relieving nausea and/or vomiting in patients the emergency department. The purpose of this study is to find out whether it is better to be treated with alcohol swab inhalation, or better to receive no additional treatment. To do this, some of the participants in this study will receive inhaled alcohol swabs, and some will receive no treatment.

What other choices are there?
You do not have to take part in this study in order to receive treatment or care. While there is no universally agreed upon standard care for the treatment of nausea/vomiting, other options may include nausea medications such as Gravol.

How many people will take part in this study?
It is anticipated that about 135 people will take part in this study, from research sites located at [blinded].

This study should take 3 months to complete and the results should be known in about 6 months.

Assignment to a Group
If you decide to participate then you will be “randomized” into one of the groups described below. Randomization means that you are put into a group by chance (like flipping a coin). There is no way to predict which group you will be assigned to. You will have a one in three chance of being placed in any group. Neither you or the research team can choose what group you will be in.

What is the study intervention?
Group 1 (Experimental Intervention):
If you are randomized to this group, you will be instructed to hold an alcohol swab 1-2cm from your nose and take one deep inhalation every 10 minutes for a total of one hour. We will record your nausea severity on a scale of 1 to 10 every 10 minutes for 30 minutes, and then every 30 minutes for a total of two hours.
Group 2 (Experimental Intervention):
If you are randomized to this group, you will be instructed to hold an alcohol swab 1-2cm from your nose and take one deep inhalation every 20 minutes for a total of one hour. We will record your nausea severity on a scale of 1 to 10 every 10 minutes for 30 minutes, and then every 30 minutes for a total of two hours.
Group 3 (Non-Experimental):
If you are randomized to this group, you will receive no intervention. We will record your nausea severity on a scale of 1 to 10 every 10 minutes for 30 minutes, and then every 30 minutes for a total of two hours.

What else do I need to know about the study intervention?
If you decide to take part in this study, your treating doctor can still decide to provide you with usual treatment, including nausea medications. If your treating doctor does decide to provide you with nausea medications, the study team will stop administering any study intervention and use your nausea scores up until the medication is given.

How long will participants be in the study?
The study intervention will last for about 1 hour. Your nausea score will be collected for a total of 2 hours.

Can participants choose to leave the study?
You can choose to end your participation in this research (called withdrawal) at any time without having to provide a reason. If you choose to withdraw from the study, you are encouraged to contact the research team.

You may withdraw your permission to use information that was collected about you for this study at any time by letting the research team know. However, this would also mean that you withdraw from the study.

Can participation in this study end early?
Study participants may be withdrawn from the study at the discretion of the research team due to a safety concern or if judged to be non-compliant with the trial procedures.

What are the risks or harms of participating in this study?
While there have been no previous studies showing side effects from inhalation of alcohol swabs, there may be side effects that are not expected, such as irritation to the nose and allergic reactions. You should discuss these with the research team. The research team will watch you closely to see if you have side effects.

What are the benefits of participating in this study?
If you agree to take part in this study, the experimental intervention may or may not be of direct benefit to you in providing relief from nausea and/or vomiting. We hope the information learned from this study will help other people with nausea and vomiting in the future.

How will participant information be kept confidential?
If you decide to participate in this study, the research team will only collect the information they need for this study.

Records identifying you at this center will be kept confidential and, to the extent permitted by the applicable laws, will not be disclosed or made publicly available, except as described in this consent document.

Authorized representatives of the following organizations may look at your original (identifiable) medical records at the site where these records are held, to check that the information collected for the study is correct and follows proper laws and guidelines.

- [blinded]Research Ethics Board who oversees the ethical conduct of this study.
- [blinded] to oversee the conduct of research at this location

Information that is collected about you for the study (called study data) may also be sent to the organizations listed above. Your name, address, email, or other information that may directly identify you will not be used. The records received by these organizations may contain your participant code, age, and sex/gender.

If the results of this study are published, your identity will remain confidential. It is expected that the information collected during this study will be analyzed and will be published/presented to the scientific community at meetings and in journals. Even though the likelihood that someone may identify you from the study data is very small, it can never be completely eliminated.

A copy of the consent form that you sign to enter the study may be included in your health record/hospital chart.

Will family doctors/health care providers know who is participating in this study?
Your family doctor/health care provider will not be informed by the study team that you are taking part in the study. You can choose to let your family doctor/health care provider know, if you like.

Will information about this study be available online?
A description of this clinical trial/study will be available on https://clinicaltrials.gov. This website will not include information that can identify you. You can search this website at any time. This research study can be found on the above listed website by using the clinical trial registration number NCT04464915.

What is the cost to participants?
Participation in this study will not involve any additional costs to you or your private health care insurance.

Are study participants paid to be in this study?
You will not be paid for taking part in this study.

What are the rights of participants in a research study?
You will be told, in a timely manner, about new information that may be relevant to your willingness to stay in this study.

You have the right to be informed of the results of this study once the entire study is complete. If you would like to be informed of the results of this study, please contact the research team.

Your rights to privacy are legally protected by federal and provincial laws that require safeguards to ensure that your privacy is respected.

By signing this form you do not give up any of your legal rights against the research team nor does this form relieve the study team of their legal and professional responsibilities. You will be given a copy of this signed and dated consent form prior to participating in this study.

What if researchers discover something about a research participant?
If any new clinically important information about your health is obtained as a result of your participation in this study, you will be given the opportunity to decide whether you wish to be made aware of that information.

Whom do participants contact for questions?
If you have questions about taking part in this study, or if you suffer a research-related injury, you can talk to your study doctor, or the doctor who oversees the study at this institution. That person is:

Dr. [blinded]
Principal Investigator Name Telephone

If you have questions about your rights as a participant or about ethical issues related to this study, you can talk to someone who is not involved in the study at all. Please contact The[blinded] Research Ethics Board, Chairperson at 613-798-5555 extension 16719.

Study Title: Isopropyl Alcohol Inhalation as Anti-Emetic Therapy in the Emergency Department

Signatures

- All my questions have been answered,
- I understand the information within this informed consent form,
- I allow access to medical records and transfer of specimens and related personal health information as explained in this consent form,
- I do not give up any of my legal rights by signing this consent form,
- I agree, or agree to allow the person I am responsible for, to take part in this study.

Signature of Participant	Printed Name	Date
Signature of Person Conducting the Consent Discussion	Printed Name and Role	Date

Study Title: Isopropyl Alcohol Inhalation as Anti-Emetic Therapy in the Emergency Department

Participant Assistance

Complete the following declaration only if the participant is <u>unable to read</u>:

☐ The consent form was read to the participant. The person signing below attests that the study as set out in this form was accurately explained to the participant, and any questions have been answered.

Signature of Impartial Witness	Printed Name	Date

Relationship to Participant

Complete the following declaration only if the participant has <u>limited proficiency in the language in which the consent form is written and interpretation was provided</u> as follows:

☐ The person signing below acted as an interpreter, and attests that this study as set out in the consent form is accurately sight translated and/or interpreted, and that interpretation was provided on questions, responses and in additional discussion arising from this process.

Signature of Interpreter	Printed Name	Date