Use of a Red-Rubber Catheter to Facilitate Nasotracheal Intubation in Adult Patients: A Prospective Randomized Controlled Trial

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Institutional Review Board

Protocol

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Institution/Funding Source: Department of Anesthesia and Pain Management – University of Texas Southwestern Medical Center

1. Introduction and Purpose:

Nasotracheal intubation is used to facilitate oropharyngeal surgery in many patients, however, epistaxis is a common complication (1). Several methods to reduce epistaxis during nasotracheal intubation have been studied in adults and children. The use of a red-rubber catheter is effective in guiding nasotracheal intubation in children, however it has not been studied in adults in a prospective, randomized, controlled trial. This study was designed to compare the effectiveness of using a red-rubber catheter versus standard, direct insertion of a thermosoftened, lubricated nasal endotracheal tube into the naris to facilitate nasotracheal intubation in adults undergoing ENT, plastics or OMFS surgery. This study will assess if the red-rubber catheter method leads to lower incidence and severity of epistaxis, and faster time to intubation compared to the current standard of care.

Hypothesis 1 – The red-rubber catheter group will have significantly lower incidence of epistaxis compared to the standard insertion group in patients undergoing nasotracheal intubation.

Primary objective: To compare the incidence of bleeding after nasotracheal intubation.

Hypothesis 2 – The red-rubber catheter group will have significantly lower severity of epistaxis compared to the standard insertion group in patients undergoing nasotracheal intubation.

Secondary objective 1: To compare the severity of epistaxis after nasotracheal intubation.

Hypothesis 3 – The red-rubber catheter group will have significantly fewer airway complications compared to the standard insertion group in patients undergoing nasotracheal intubation.

Secondary objective 2: To compare the rate of complications during nasotracheal intubation.

Hypothesis 4 – The red-rubber catheter group will have significantly lower time to intubation than the standard insertion group.

Secondary objective 3: To compare the time to intubation during nasotracheal intubation.

Hypothesis 5 – The red-rubber catheter group will have significantly less pain postoperatively than the standard insertion group.

Secondary objective 4: To compare postoperative pain after nasotracheal intubation.

2. Background

Nasotracheal intubation (NTI) is commonly utilized in oropharyngeal surgeries to provide better access to the surgical field than traditional endotracheal intubation (1). NTI is also commonly used in patients with degenerative cervical spine pathology, intraoral mass lesions or structural abnormalities, and limited mouth opening (2). NTI is generally contraindicated in cases of suspected epiglottitis, midface instability, basilar skull fractures, and coagulopathy. Minor contraindications include nasal polyps, foreign bodies, recent nasal or facial surgery, and history of frequent epistaxis (1). Some complications of NTI that have been described in the literature include epistaxis, damage to a nasal turbinate or the cribriform plate, retropharyngeal dissection, and even intracranial placement of the nasotracheal tube (3-6). One of the most common complications of NTI is epistaxis, with a reported incidence of up to 86% (7).

In adults, NTI is typically performed by using phenylephrine or oxymetazoline as a vasoconstrictor, and an adequately lubricated and often, thermosoftened, nasotracheal tube (NETT). The NETT is held perpendicular to the face and inserted below the inferior turbinate with the bevel of the tube facing away from the turbinate. When the tip of the tube is seen in the oropharynx, direct laryngoscopy is used to visualize the cords and pass the tube into the trachea. Magill forceps are often used to facilitate this final step (8).

Several studies have evaluated ways to improve the way NTI is performed and minimize epistaxis. Enk et al. utilized a Wendl tube attached to the end of the NETT to guide intubation, with removal of the Wendl tube once the NETT was in the oropharynx. They found that using the Wendl tube as a "pathfinder" significantly reduced the incidence and severity of bleeding and decreased postoperative pain, although this method took longer to perform compared to insertion of the NETT without a pathfinder (9). Lim et al. used a nasogastric tube as a guide to facilitate NTI and found that with the nasogastric tube-guided method the NETT more often passed under the inferior turbinate, was associated with lower incidence and severity of epistaxis, and required fewer manipulations to place (10). Seo et al. obturated the ETT with an inflated esophageal stethoscope and thermosoftened the NETT, finding that the severity of epistaxis during NTI was lowest when using the obturated and thermosoftened NETT (7). A recent study by Vadhanan and Tripaty compared the use of a flexible bougie to guide NTI, with the bougie-guided technique having significantly less bleeding than the conventional method but taking longer to perform (11). Another study had similar findings and additionally noted that there was no difference in the first attempt and overall success rates of NTI with the bougie-guided or conventional method (12).

In children, NTI is commonly performed using a red-rubber catheter (RRC) as a guide, and its efficacy has been studied in randomized controlled trials. Watt et al. compared room temperature and warmed NETT to the RRC method in children undergoing dental surgery and found that the RRC method had lower incidence of higher severity bleeding. Although they found that the RRC method took longer, hemoglobin oxygen desaturation did not occur in the time to intubation. They

go on to discuss the mechanism by which the RRC method may reduce epistaxis, mainly by shielding the nasal mucosa from the stiff leading edge of the NETT (13). An earlier study by Elwood et al. comparing the RRC method to the thermosoftened nasotracheal tube alone reported similar results, with the RRC group having significantly less obvious bleeding. While the RRC method took longer to perform, it also took fewer attempts for successful placement (14). A recent literature review by Lera et al. on techniques for NTI in children and adults examined 15 articles, 4 of which studied the RRC method specifically. They determined that overall this technique is associated with decreased trauma to the nasopharynx, bleeding, and postoperative pain (15).

To date, there have been no randomized controlled trials that have evaluated the efficacy of using a RRC to guide NTI in adults, although there is data to support the use of the RRC method in children. In addition, in these trials the control was the direct insertion of a nasotracheal tube into the naris, which is a common practice in adult patients. We hypothesize that RRC-guided NTI will be associated with significant lower incidence and severity of epistaxis in adult patients undergoing surgery requiring nasotracheal intubation. We also hypothesize that compared to the standard technique, the RRC method will take significantly less time to perform, will be associated with less postoperative pain, and will have fewer associated complications.

3. Concise Summary of Project:

The study population for this prospective randomized controlled trial will consist of male and female adult subjects over the age of 18 having surgery requiring NTI. Consent will be obtained by study personnel. Eligible patients will be screened by study personnel up to 1 week prior to scheduled surgery. Informed consent will be obtained in the preoperative holding area. This is a multicenter study. The MD Anderson Center is other site of the study. Each study site will enroll 56 subjects. A total of 112 subjects will be randomized to either the RRC group or control group. Oxymetazoline nasal spray will be administered with 1 spray per nostril preoperatively. Premedication with glycopyrrolate 0.2 mg and benzodiazepine at discretion of provider will be given preoperatively. Subjects will then be brought into the operating room and placed on all standard ASA monitors (BP cuff, EKG, pulse oximetry). One spray of oxymetazoline per nostril will again be administered. Standard preoxygenation will be used with a face mask and 100% O2. After induction of anesthesia, provider will confirm mask ventilation and 1 more spray of oxymetazoline will be administered per nostril. Intubation will first be attempted via a naris (13). Size 6.5 nasotracheal RAE tubes (Shiley Nasal RAE Tracheal Tube with TaperGuard Cuff, manufactured by Coviden llc, Mansfield, MA 02048) will be used in female patients and size 7.5 in males (16). The tubes will be thermosoftened by allowing them to sit in warm saline prior to use (18). Water-based lubrication will be used for dilation and intubation. Time from insertion of RRC or NETT into nasal passage to first recording of end-tidal CO2 will be recorded. Direct video laryngoscopy will be used to facilitate placement of the nasotracheal RAE tube. Five minutes after intubation, a non-collaborating anesthesia provider blinded to the method of intubation will grade the severity of bleeding by performing direct video laryngoscopy, inspecting the posterior pharynx and using a scale described originally by Sugiyama et al (19) and again by Earle et. al (20)- no epistaxis (no blood observed on either the surface of the tube or the posterior pharyngeal wall); mild epistaxis (blood apparent on the surface of the tube or posterior pharyngeal wall); moderate epistaxis (pooling of blood on the posterior pharyngeal wall); and severe epistaxis (a large amount of blood in the pharynx impeding nasotracheal intubation—before the epistaxis assessor enters the

operating room, requiring suction for intubation or necessitating urgent orotracheal intubation.) Degree of nasal pain on the side of intubation will be rated on a numerical rating scale at 30 and 60 minutes in the post-anesthesia care unit (9).

The removal/reinsertion of the laryngoscope and endotracheal tube or switching of the laryngoscopist will be evaluated as a new intubation attempt.

The study duration starts from operating room preoperative holding area admission to discharge from the Post Anesthesia Care Unit (PACU).

RRC group: The funnel end of a RRC (Bard All-Purpose Urethral Catheter, manufactured by C. R. Bard, Inc, Covington, GA 30014 USA) will be securely attached to a room-temperature nasotracheal tube. A 20 Fr RRC will be used with the size 7.5 nasotracheal RAE tube and an 18 Fr RRC will be used with the size 6.5 nasotracheal RAE tube. The tubes will be warmed in saline prior to use (18). Water-based lubrication will be applied to the RRC. The rounded end of the catheter will be introduced into a naris and advanced to the posterior oropharynx and visualized with a laryngoscope. The catheter will then be removed from the end of the nasotracheal tube and withdrawn through the mouth. The nasotracheal tube will then be guided into the trachea past the vocal cords under direct visualization with CMAC video laryngoscope MAC 3 or 4 blade with or without the assistance of Magill forceps as determined by the provider (17).

Control group: The NETT will be warmed in saline prior to use (18). Water-based lubrication will be applied on the nasotracheal RAE tube. The nasotracheal tube will be inserted into the nasal passage and advanced into the oropharynx. The nasotracheal tube will then be guided into the trachea past the vocal cords under direct visualization with CMAC video laryngoscope MAC 3 or 4 blade with or without the assistance of Magill forceps as determined by the provider.

Outcome Measures:

- Incidence of bleeding in posterior oropharynx
- Severity of bleeding in posterior oropharynx
- Need to suction the posterior oropharynx to facilitate intubation
- Time from first insertion of catheter or nasal RAE tube to ETCO2
- Number of intubation attempts
- Recruitment of the other naris for intubation
- Use of Magill forceps to facilitate intubation
- Use of rescue technique (fiberoptic, oral intubation) to facilitate intubation
- Patient rating of nasal pain on side of intubation
- Anesthesiologist intervention outside of protocol
- Premature termination of procedure
- Unplanned hospital admission
- Unanticipated complications

4. Study Procedures:

- Identify and screen patients for study eligibility based on inclusion and exclusion criteria.
- Randomize subjects to the RRC or control group in a 1:1 ratio according to a computer-generated block randomization list (multi-center). (Research only)
- Administer premedication in the preoperative area (standard of care)
- Administer 1 spray of oxymetazoline per nostril in preoperative area (standard of care).
- Perform patency test in the preoperative area to determine which nares to use for initial attempt (standard of care).
- All standard monitoring (BP, EKG, and pulse oximeter) will be placed on all patients in the operating room (standard of care).
- Administer 1 spray of oxymetazoline per nostril prior to preoxygenation in the operating room (standard of care).
- Apply standard preoxygenation with full face mask (standard of care).
- Patients will undergo standardized NTI facilitated by RRC or direct insertion based on study group. Both procedures for nasal intubation are considered standard of care.
- Time from insertion of RRC or NETT into nasal passage to first recording of end-tidal CO2 on monitor will be recorded (standard of care).
- Incidence and severity of epistaxis will be graded by a member of the anesthesia team according to a scale previously described and recorded (19, 20) (Research only).
- Anesthesia providers will record the number of intubation attempts, recruitment of the other naris, premature termination of the procedure, use of Magill forceps and use of rescue techniques to facilitate intubation, and other interventions, complications, or deviations from protocol during intubation in the EMR using a quick note.
- Postoperatively patients will be asked to rate their level of nasal pain on the side (left or right) that NTI was performed using a numerical rating scale at 30 and 60 minutes post emergence from anesthesia. Pain will be evaluated with Numeric Rating Scale (0=no pain and 10- worst pain imaginable). (Research only).

5. Sub-Study Procedures:

- N/A

6. Criteria for Inclusion of Subjects:

- Age > 18, male and female
- Subjects undergoing surgery requiring NTI
- ASA 1-3

7. Criteria for Exclusion of Subjects:

- History of anticoagulant use or coagulopathy
- History of latex allergy
- History of difficult airway
- Anticipated difficult airway requiring awake intubation
- Abnormal anatomy of the nasal passage (due to prior trauma, surgery, congenital defects, etc.) or basilar skull fracture
- Patients unable to be placed in the sniffing position

- Morbid obesity with BMI > 40
- Pregnancy
- ASA 4

8. Sources of Research Material:

- Subjects undergoing surgery requiring NTI
- Electronic Medical Record
- Anesthesia Reports
- PHI including name, medical record number, contact information including demographic information including age, gender, race, birth date, weight, height, BMI and medical and surgical history, medication list, ASA classification.
- **Procedural intubation-related variables:** incidence and severity of epistaxis, time from beginning intubation (insertion of nasopharyngeal airway or NETT into nasal passage) to ETCO2, subjective pain rating using validated scale, number of attempts, whether the provider had to attempt on the other naris, use of Magill forceps to facilitate endotracheal intubation, use of rescue techniques to facilitate intubation, and any anesthesiologist modifications, interventions, or deviations from protocol necessary to successfully intubate or address complications (i.e., suctioning, insertion of an oral/nasal airway, conversion to oral endotracheal intubation, change in tube size etc.).
- Modified Cormack-Lehane classification: Grade1-full view of glottis; Grade2a-Partial view of glottis; 2b-Only posterior view of glottis; Grade 3-Only epiglottis seen, none of glottis seen; Grade 4- Neither glottis, nor epiglottis seen.
- C MAC Laryngoscope blade type (3 or 4)
- **Biometric variables:** oxygen saturation (baseline) and the lowest SpO2 during intubation Duration of anesthesia and procedure
- **Postoperative Recovery:** time spent in PACU, pain score at 30 and 60 minutes, unanticipated complications and hospital admissions.

9. Recruitment Methods and Consenting Process:

Subjects will be identified for potential eligibility by reviewing the weekly main operating room surgery schedule. Eligible subjects will be patients of the PI, co-investigators or other anesthesiologists. Other anesthesiologists will be contacted verbally or by email 1 day prior to the scheduled surgery for their permission to enroll the subjects. A ``Dear Doctor Letter'' will be sent to physicians via email. Without the confirmation of their consent, investigators will not enroll the subjects.

A designated team of study personnel will be responsible for screening, consenting and enrolling potential subjects. Consenting and enrollment will take place in the preoperative holding area. Information about the study will be given in a pressure-free, confidential private area in a face-to-face meeting and the voluntary nature of the research will be emphasized to the subjects.

The purpose of the study will be explained to the subject. Potential risks and complications will be reviewed. Adequate time will be given for the subject to consider whether to participate in the

study and all questions will be answered by a member of the study team. If the subject agrees to participate, then he or she will sign the consent form and HIPAA Authorization Form prior to any study procedures. In the case of Spanish-only speaking subjects, a live interpreter will be utilized for the above process and the consent and HIPAA Authorization Form will be provided to the subject in Spanish. Subjects will receive a copy of the signed documents.

10. Potential Risks:

This study has minimal risk. The anesthetic management in each group will not differ from the current standard of care.

Risk for RRC: There may be risk for mucosal injury and bleeding with RRC-guided NTI. This risk is not anticipated to be higher than for standard NTI in adults.

Psychological Stress: Some of the questions related to the study may make the subject feel uncomfortable. Subjects may refuse to answer any of the questions, take a break, or stop participation in the study at any time.

Loss of Confidentiality: Any time information is collected; there is a potential risk of loss of confidentiality. Every effort will be made to keep your information confidential.

11. Subject Safety and Data Monitoring:

Investigators will ensure patient safety throughout the procedure. This will include following all standards of care with regard to conducting a safe anesthetic and intubation in the operating room. All standard ASA monitors will be used and proper interventions by the providers will be carried out for complications or difficult intubation. Subjects will recover from the anesthetic in the post-anesthesia care unit. All data will be collected by the anesthesia providers and study personnel.

Data and Safety monitoring plan includes the formation of a Data and Safety Monitoring Board (DSMB). As independent research expert, Board Certified Anesthesiologists Dr. Irina Gasanova and Dr. Omaira Azizad will review safety and data information. The DSMB will also obtain the results of the interim analysis after 50% enrollment.

12. Procedures to Maintain Confidentiality:

All participants will be given an identification number such that identifiable, personal information will not be used. There will be link to MR number. Subjects will be identified to collect data and verify the data. Every effort will be made to keep all data collection sheets confidential and any electronic data sets will be password protected and secure. Electronic documents will be de-identified according to information security policies. Paper documents will be shredded.

13. Potential Benefits:

There is no benefit to subjects. Use of the RRC may lead to a significant decrease in epistaxis and pain in patients undergoing NTI. Information gained from this study will potentially improve future outcomes in this patient population through reducing complications of nasotracheal intubation.

14. Data Sharing;

MD Anderson site will provide deidentified protocol requiring data via REDCap. UT Southwestern team who have access to MD Anderson Center RedCap will download the de-identified data. REDCap (https://redcap.mdanderson.org) is hosted on a secure server by MD Anderson Cancer Center's Department of Oncology Care & Research Information Systems. REDCap has undergone an annual Governance Risk & Compliance Assessment (since May 2014) by MD Anderson's Information Security Office and found to be compliant with HIPAA, Texas Administrative Codes 202-203, University of Texas Policy 165, federal regulations outlined in 21CFR Part 11, and UTMDACC Institutional Policy #ADM0335.

Those having access to the data include the study PI's and research team personnel of both study sites. Users are authenticated against MDACC's Active Directory system. External collaborators are given access to the database once approved by the PI, with their access expiring in 6 months, but renewable in 6 months increments at the request of the PI. The application is accessed through Secure Socket Layer (SSL).

15. Biostatistics: (omit this section for peer-reviewed research such as cooperative group, or NIH- sponsored studies, and for industry-sponsored research which has been submitted to FDA)

Assuming the incidence of bleeding to be 50% and 24% in the control and RRC group, respectively, a sample size of 53 subjects per group (total n=106) are needed. This study is designed to have 80% power with alpha = 5%, two-sided. Assuming a dropout of 5%, a total of 112 subjects (56 in each arm) are required for this study. The sample size calculation was based on the chisquare tests.

Baseline characteristics (Demographics, Comorbidities) of all randomized patients will be summarized and presented in tables. Categorical variables will be presented as proportions and continuous variables as mean (SD) or median (range) as appropriate. The baseline differences between the two treatment arms will be assessed by Chi square/Fisher exact tests for proportions and Student t-test/Wilcoxon ranksum test for continuous variables as appropriate.

An intention to treat analysis will be conducted to assess the primary endpoint of bleeding. Logistic regression analysis will be conducted to model the primary endpoint between the treatment groups accounting for other confounders. Individual logistic regressions analyses will be conducted to model the secondary outcomes adjusting for treatment groups and other confounders. A univariate and a multivariable linear regression analysis will be conducted for those secondary outcomes, which are measured as continuous variables. A per protocol analysis will also be conducted where

patients with protocol violations will be excluded from the analysis. All analyses will be done using SAS 9.4 and $p<0.05$ will be considered statistically significant.

15. References:

1. Chauhan, V. and Acharya, G. (2016) Nasal Intubation: A Comprehensive Review. Indian Journal of Critical Care Medicine, 20,662-667. doi:10.4103/0972-5229.194013
2. Hall, C.E. and Shutt, L.E. (2003) Nasotracheal Intubation for Head and Neck Surgery. Anaesthesia, 58, 249-256. doi:10.1046/j.1365-2044.2003. 03034.x
3. Patiar S, Ho EC, Herdman RC. Partial middle turbinectomy by nasotracheal intubation. Ear Nose Throat J 2006; 85:380, 382-3
4. Prasanna, D. and Bhat, S. (2014) Nasotracheal intubation: an overview. Journal of Maxillofacial and Oral Surgery, 13, 366-372. doi:10.1007/s12663-013-0516-5
5. Terumitsu, M., Hirahara, M., & Seo, K. (2017). Retropharyngeal Dissection by Parker Flex-Tip Nasal Endotracheal Tube. Anesthesia Progress, 64(4), 240–243. doi:10.2344/anpr-64-03-05
6. Allen, F., Riopelle, J., & Sinha, A. (2011). Intracranial Placement of a Nasotracheal Tube in a Patient with Goldenhar Syndrome Associated with Cribriform Plate Agenesis. Anesthesia & Analgesia, 112(1), 198-200. doi:10.1213/ane.0b013e3181fca689
7. Seo, K.S., Kim, J.-H., Yang, S.M., Kim, H.J., Bahk, J.-H. and Yum, K.W. (2007) A New Technique to Reduce Epistaxis and Enhance Navigability during Nasotracheal Intubation. Anesthesia & Analgesia, 105, 1420-1424. https://doi.org/10.1213/01.ane.0000281156.64133.bd
8. Butterworth, J. F., Mackey, D. C., Wasnick, J. D., Morgan, E. G., & Mikhail, M. S. (2013). Morgan & Mikhail's Clinical Anesthesiology (5th ed.). New York, NY: McGraw-Hill.
9. Enk, D., Palmes, A.M., Van Aken, H. and Westphal, M. (2002) Nasotracheal Intubation: A Simple and Effective Technique to Reduce Nasopharyngeal Trauma and Tube Contamination. Anesthesia & Analgesia, 95, 1432-1436. doi:10.1097/00000539-200211000-00061
10. Lim, C.W., Min, S.W., Kim, C.S., Chang, J.E., Park, J.E. and Hwang, J.Y. (2014) The Use of a Nasogastric Tube to Facilitate Nasotracheal Intubation: A Randomised Controlled Trial. Anaesthesia, 69, 591-597. Doi:10.1111/anae.12627
11. Vadhanan, P., & Tripaty, D. K. (2018). Effect of Bougie-Guided Nasal Intubations upon Bleeding: A Randomised Controlled Trial. Turkish Journal of Anesthesia and Reanimation, 96-99. doi:10.5152/TJAR.2017.51333
12. Abrons, R. O., Zimmerman, M. B., & El-Hattab, Y. M. (2017). Nasotracheal intubation over a bougie vs. non-bougie intubation: A prospective randomised, controlled trial in older children and adults using videolaryngoscopy. Anaesthesia, 72(12), 1491-1500. doi:10.1111/anae.14029
13. Watt, S., Pickhardt, D., Lerman, J., Armstrong, J., Creighton, P.R. and Feldman, L. (2007) Telescoping Tracheal Tubes into Catheters Minimizes Epistaxis during Nasotracheal Intubation in Children. Anesthesiology, 106,238-242. doi:10.1097/00000542-200702000-00010
14. Elwood, T., Stillions, D.M., Woo, D.W., Bradford, H.M. and Ramamoorthy, C. (2002) Nasotracheal Intubation: A Randomized Trial of Two Methods. Anesthesiology, 96, 51-53. doi:10.1097/00000542-200201000-00014

15. Lera, S., Machan, M. and Derefaka, G. (2017) A Safer Technique for Nasal Intubation: A Literature Review. Open Journal of Anesthesiology, 7, 275-285.
16. Ji, S. (2017). Estimation of optimal nasotracheal tube depth in adult patients. Journal of Dental Anesthesia and Pain Medicine,17(4), 307. doi:10.17245/jdapm.2017.17.4.307
17. Wong, A., Subar, P., Witherell, H. and Ovodov, K.J. (2011) Reducing Nasopharyngeal Trauma: The Urethral Catheter-Assisted Nasotracheal Intubation Technique. Anesthesia Progress, 58, 26-30. doi:10.2344/0003-3006-58.1.26
18. Kim, Y.C., Lee, S.H., Noh, G.J., Yeom, J.H., Shin, W.J., Lee, D.H., Ryu, J.S., Park, Y.S., Cha, K.J., Lee, S.C. Thermosoftening treatment of the nasotracheal tube before intubation can reduce epistaxis and nasal damage. (2000) Anesthesia & Analgesia, 91(3):698-701. PMID:10960403.
19. Sugiyama K, Manabe Y, Kohjitani A. A styletted tracheal tube with a posterior-facing bevel reduces epistaxis during nasal intubation: a randomized trial. Can J Anesth 2014; 61: 417-22.
20. Earle R, Shanahan E, Vaghadia H, Sawka A, Tang R. Epistaxis during nasotracheal intubation: a randomized trial of the Parker Flex-Tip TM nasal endotracheal tube with a posterior facing bevel *versus* a standard nasal RAE endotracheal tube. Can J Anesth 2017; 64: 370-375.

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Consent to be part of a Research Study
To be conducted at
Parkland Health & Hospital System

Information about this form

You may be eligible to take part in a research study. This form gives you important information about the study.

Please take the time to review this information carefully. You should talk to the researchers about the study and ask them any questions you may have. You may also wish to talk to others (for example, your friends, family, or a doctor) about your participation in this study. If you decide to take part in the study, you will be asked to sign this form. Before you sign this form, be sure you understand what the study is about, including the risks and possible benefits to you.

Please tell the researchers or study staff if you are taking part in another research study.

Your doctor is a research investigator in this study. S/he is interested in both your medical care and the conduct of this research study. At any time, you may discuss your care with another doctor who is not part of this research study. You do not have to take part in any research study offered by your doctor.

Voluntary Participation - You do not have to participate if you don't want to. You may also leave the study at any time. If you decide to stop taking part in this research study, it will not affect your relationship with the UT Southwestern staff or doctors. Whether you participate or not will have no effect on your legal rights or the quality of your health care.

If you are a medical student, fellow, faculty, or staff at the Medical Center, your status will not be affected in any way.

General Information – "Who is conducting this research?"

Principal Investigator
The Principal Investigator (PI) is the researcher directing this study; the PI is responsible for protecting your rights, safety and welfare as a participant in the research. The PI for this study is David Mercier MD, Department of Anesthesiology and Pain Management at UT Southwestern Medical Center and Parkland Health Hospital System.

Purpose – "Why is this study being done?"

Nasal intubation is the placement of a breathing tube from nose into your trachea to provide an open airway to your lungs during anesthesia. This type of intubation is preferred when the surgeon needs access to your mouth and jaw.

Investigational Use of Drug or Device
This study involves the use of an investigational device called a Bard All-Purpose Urethral Catheter. "Investigational" means that the device has not yet been approved by the U.S. Food & Drug Administration (FDA) specifically for nasal endotracheal intubation guidance, though it is commonly used for this purpose by anesthesia providers.

You are being asked to participate in a research study in airway management that involves nasotracheal intubation. Nasotracheal intubation is usually performed by placing a soft breathing tube through the nasal passage into your trachea. There are several methods and anesthesiologist can use to place this tube. However, most methods can cause nose bleeding (epistaxis). The investigators will compare two nasal intubation techniques, the traditional method versus Red-Rubber tube guidance, used more commonly in children.

The researchers hope to learn which nasal intubation technique will cause less nose bleeding (epistaxis).

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.

Information about Study Participants – "Who is participating in this research?"

You are being asked to be a participant in this study because you are undergoing surgery that requires placement of a tube through your nasal passage.

How many people are expected to take part in this study?
This is a multicenter clinical trial. Study participants will be enrolled at Parkland Health Hospital System and the MD Anderson Center. Up to 130 participants will be enrolled in this study and **96** study participants will take part at MD Anderson Center.

Information about Study Procedures – "What will be done if you decide to be in the research?"

Screening Procedures

- Physical examination: The results of the physical examination done as part of your standard care will be used.
- If you are capable of becoming pregnant, a pregnancy test will also be done as part of your standard care before you participate in the study.
- Your medical record will be reviewed to determine your eligibility for the study.

The results of the screening exams, tests, and/or procedures will be reviewed to determine whether you will be allowed to continue in the study. If you are not allowed to continue in the study, the researcher will discuss the reasons with you and will discuss other possible options.

Assignment to Study Groups –
When it is determined that you are eligible for the study, you will be assigned by chance (like flipping a coin) to one of nasal intubation study groups, the traditional nasal intubation technique versus nasotracheal intubation with Red-rubber tube guidance.

- **The control technique (traditional method)**: A tube called as nasal endotracheal tube will be placed through your nasal passage to back of your mouth (oropharynx). The nasotracheal tube will then be guided into the trachea (larger airway) under direct visualization with a video assisted laryngoscope, which is a small device to look into your throat and larynx.

- **Red-rubber tube guidance**: A soft red-rubber tube will be placed into your nose to guide the longer tube through your nasal passage to the back of your mouth. Then, the nasotracheal tube will be guided into the trachea (larger airway) under direct visualization with a video assisted laryngoscope. This technique is commonly utilized in children to decrease trauma to your nose.

You will not know whether you are receiving the traditional method or Red-rubber tube method for airway placement through your nasal passage. The researchers will know which method will be used.

Both procedures for nasal intubation described are considered standard of care. In the traditional method, a lubricated nasal endotracheal tube softened with warm water is placed into the patient's nostril without Red Rubber Tube guidance. Red Rubber Tube guidance is used more commonly in children and is also a standard of care option for your anesthesiologist.

Study Procedures - as a participant, you will undergo the following procedures:

- You will be randomized to one of the study groups. Both techniques for nasotracheal intubation are considered standard of care. Whether you are in the study or not, you will undergo nasal endotracheal intubation by one of these methods. A tube will be inserted through your nostril into your trachea (an airway from your nose to your lung) for airway management during anesthesia.
- The Investigator will evaluate the back of your mouth for any signs of bleeding.
- You will be asked to grade your pain after surgery on a scale of 1-10 (0=no pain and 10=worst pain imaginable). Your pain will be evaluated at 30 minutes and 60 minutes after you enter the Post-Anesthesia Care Unit (PACU).
- The severity of nasal bleeding will be evaluated immediately after placement of the nasal endotracheal tube.
- The risks of the study are listed in the risk section. You will be monitored for any side effects during the study period.

- You will be in the study during surgery until discharge from anesthesia care unit (PACU).

Could your participation end early? There are several reasons why the researchers may need to end your participation in the study (early withdrawal). Some reasons are:
- The researcher believes that it is not in your best interest to stay in the study.
- You become ineligible to participate.
- Your condition changes and you need treatment that is not allowed while you are taking part in the study.
- You do not follow instructions from the researchers.
- The study is stopped.

The researchers will discuss your options for medical care when your participation in this study ends.

Risks – "What are the risks of participation in the research?"

Risks from the research
The investigators have designed this study to learn how well the nasal intubation with the Red-rubber guidance compares to the traditional nasal intubation method. The Red-Rubber tube group may not be as good as the most commonly accepted traditional techniques.

Risks from the specific research procedures
There are risks to taking part in this research study. One risk is that you may have side effects while on the study.

The risk of the red rubber tube technique:
- **Nose bleeding (epistaxis).** This is a common side effect of nasal intubation. The investigators expect less nasal bleeding using red-rubber tube guidance. There may be a risk for mucosal injury and bleeding with Red Rubber Tube-guided nasotracheal intubation. Water based lubricant will be used to decrease the risk of nasal trauma. This risk is not anticipated to be higher than that for standard nasal intubation in adults.

The risk of the traditional nasal intubation technique:
- **Nose bleeding**. This is a common side effect of nasal intubation. Water based lubricant will be used to decrease nasal trauma.

Side effects from this study will usually go away soon after nasal intubation. In some cases, side effects can be long lasting or may cause repeated nasal bleeding.

Everyone taking part in the study will be watched carefully for any side effects. However, the study doctors aren't always aware of all the side effects that may happen. Be sure to tell your study doctor immediately about any side effect that you have while taking part in the study.

The following section will describe the risks related to each your participation in this research study. You should talk to your study doctor about any side effects or other problems that you have while taking part in the study.

For more information about risks and side effects, ask one of the researchers or study staff.

Are there Risks related to withdrawing from the study?
If you decide to withdraw from this study early, please discuss your decision with the principal investigator. The researcher may ask you to complete study withdrawal procedures. There is no risk to you if you do not complete the final withdrawal procedures and you can choose not to participate in them.

Are there risks if you also participate in other research studies?
Being in more than one research study at the same time, may increase the risk to you. It may also affect the results of the studies. You should not take part in more than one study without approval from the researchers.
Alternative procedures or course of treatment – "What other options are there to participation in this study?"

Your other choices may include placement of a thermosoftened lubricated nasal endotracheal tube into your nostril without red rubber tube guidance.

Payments – Will there be any payments for participation?

There is no compensation participation of this research

What if a research-related injury occurs?
The researchers have taken steps to minimize the known or expected risks. However, you may still experience

problems or side effects, even though the researchers are careful to avoid them. In the event of a research-related injury or if you experience an adverse reaction, please immediately contact your study doctor. See the section "Contact Information" for phone numbers and additional information. You may also need to tell your regular doctors.

If you are injured or made sick from taking part in this research study, medical care will be provided. This care may be billed to you or your insurance. Depending on the circumstances, this care may be provided at no cost to you. We have no plans to give you money if you are injured. The investigator can provide you with more information.

If you sign this form, you do not give up your right to seek additional compensation if you are harmed as a result of being in this study.

Benefits – "How could you or others benefit from your taking part in this study?"

The possible benefit of your participating in this study is a decrease in nose trauma and nose bleeding *which is likely to contribute to the well-being of you after surgery*. There is no guarantee or promise that you will receive any benefit from this study.

We hope the information learned from this study will benefit other people with similar conditions in the future.

Costs – Will taking part in this study cost anything?

You or your health insurance company will be responsible for the cost of treatments and procedures that would be done whether or not you took part in this study, such as nasal tracheal intubation with the traditional technique or using red-rubber tube guidance, or anesthesia for surgery. It is important to understand that some insurance companies do not cover some costs (for example, approved drugs used in a way different from the package instructions). If your insurance company does not cover these treatments or procedures, you will be required to pay for them. "Ask the researchers if you have any questions about what it will cost you to take part in this study (for example bills, fees, or other costs related to the research)".

Confidentiality – How will your records be kept confidential?

Information we learn about you in this study will be handled in a confidential manner, within the limits of the law. If we publish the results of the study in a scientific journal or book, we will not identify you. The Institutional Review Board and other groups that have the responsibility of monitoring research may want to see study records that identify you as a subject in this study.

HIPAA Section:

Research policies require that private information about you be protected and this is especially true for your health information. However, the law sometimes allows or requires others to see your information. The information given below describes how your privacy and the confidentiality of your research records will be protected in this study. Medical information collected during this study and the results of any test or procedure that may affect your medical care may be included in your medical record. The information included in your medical record will be available to health care providers and authorized persons including your insurance company.

What is Protected Health Information (PHI)?

Protected Health Information is information about a person's health that includes information that would make it

possible to figure out whose information it is. According to the law, you have the right to decide who can see your protected health information. If you choose to take part in this study, you will be giving your permission to the investigators and the research study staff (individuals carrying out the study) to see and use your health information for this research study. In carrying out this research, the health information we will see and use about you will include:

Your medical history, information that we get from your medical record, information contained in your underlying medical records related to your medical history and treatments prior to the study, information that is created or collected during your participation in the study including medical and treatment history including nasal bleeding, intubation-related information, any adverse event during intubation and surgery, anesthetic agent used for general anesthesia, oxygen and carbon dioxide concentration in the endotracheal tube, and information you give us during your participation in the study such as demographic information like your age and pain score.

We will get this information by asking you, asking your doctor, and by looking at your chart at Parkland Hospital.

How will your PHI be shared?

Because this is a research study, we will be unable to keep your PHI completely confidential. We may share your health information with people and groups involved in overseeing this research study including:

- The following collaborators at other institutions that are involved with the study: Parkland Health Hospital System.
- The members of the local research team.
- The Institutional Review Board, Human Research Protection Program Office and the Compliance Office of the University of Texas Southwestern Medical Center, and other groups that oversee how research studies are carried out.
- The Research offices at the University of Texas Southwestern Medical Center, Parkland Health and Hospital System.
- The Food and Drug Administration (FDA) and other U.S. and international governmental regulatory agencies involved in overseeing drug or device research.
- Representatives of domestic and foreign governmental and regulatory agencies may be granted direct access to your health information for oversight, compliance activities, and determination of approval for new medicines, devices, or procedures.

If you decide to participate in this study, you will be giving your permission for the groups named above, to collect, use and share your health information. If you choose not to let these groups collect, use and share your health information as explained above, you will not be able to participate in the research study.
Parts of your PHI may be photocopied and sent to a central location or it may be transmitted electronically, such as by e-mail or fax. The groups receiving your health information may not be obligated to keep it private. They may pass information on to other groups or individuals not named here

How will your PHI be protected?

In an effort to protect your privacy, the study staff will use code numbers instead of your name to identify your health information. Initials and numbers will be used on any photocopies of your study records, and other study materials containing health information that are sent outside of the Parkland Hospital for review or testing. If the results of this study are reported in medical journals or at meetings, you will not be identified.

Do you have to allow the use of your health information?
You do not have to allow (authorize) the researchers and other groups to see and share your health information. If you choose not to let the researchers and other groups use your health information, there will be no penalties but you will not be allowed to participate in the study.

After you enroll in this study, you may ask the researchers to stop using your health information at any time. However, you need to say this in writing and send your letter to **David Mercier MD** with the Department of Anesthesiology and Pain Management at UT Southwestern Medical Center (5323 Harry Hines Blvd, Dallas, TX, 75390-9068). If you tell the researchers to stop using your health information, your participation in the study will end and the study staff will stop collecting new health information from you and about you for this study. However, the study staff will continue to use the health information collected up to the time they receive your letter asking them to stop.

Can you ask to see the PHI that is collected about you for this study?
The federal rules say that you can see the health information that we collect about you and use in this study. Contact the study staff if you have a need to review your PHI collected for this study.

Because of the type of research, you can only access your PHI when the study is done. At that time, you have the right to see and copy the medical information we collect about you during the study, for as long as that information is kept by the study staff and other groups involved.

How long will your PHI be used?
By signing this form, you agree to let us use and disclose your health information for purposes of the study until the end of the study. This permission to use your personal health information expires when the research ends and all required study monitoring is over.

Contact Information – Who can you contact if you have questions, concerns, comments or complaints?

If you have questions now, feel free to ask us. If you have additional questions, concerns, comments or complaints later or you wish to report a problem which may be related to this study please contact: **David Mercier** MD with the Department of Anesthesiology and Pain Management at UT Southwestern Medical Center (5323 Harry Hines Blvd, Dallas, TX, 75390-9068).

To use the pager, you need to have a touch tone (push button) telephone. Dial the pager number as you would any phone number. When you hear 3 short high-pitched beeps, dial in the number where you want the doctor to call you back. Push the # button, hang up and wait for the doctor to return your call.
Primary contact:
David Mercier MD can be reached at 214-645-3479 during regular business hours and at any time at 214-786-0313.
If primary is not available, contact
Christina Riccio MD can be reached at 214-786-3541.

The University of Texas Southwestern Medical Center Human Research Protection Program (HRPP) oversees research on human subjects. HRPP and Institutional Review Board (IRB) representatives will answer any questions about your rights as a research subject, and take any concerns, comments or complaints you may wish to offer. You can contact the HRPP by calling the office at 214-648-3060.

Research Consent & Authorization Signature Section

If you agree to participate in this research and agree to the use of your protected health information in this research, sign this section. You will be given a copy of this form to keep. You do not waive any of your legal rights by signing this form.

SIGN THIS FORM ONLY IF THE FOLLOWING STATEMENTS ARE TRUE:

- You have read (or been read) the information provided above.
- Your questions have been answered to your satisfaction about the research and about the collection, use and sharing of your protected health information.
- You have freely decided to participate in this research, or you are voluntarily giving your consent for another person to participate in this study because you believe this person would want to take part if able to make the decision and you believe it is in this person's best interest.
- You understand that a copy of this signed consent document, information about this study, and the results of any test or procedure that may affect your medical care, may be included in your medical record. Information in your medical record will be available to health care providers and authorized persons including your insurance company.
- You authorize the collection, use and sharing of your protected health information (another person's protected health information) as described in this form.

Adult Signature Section

Printed Name of Participant	Signature of Participant	Date	Time AM PM
Printed Name of Person Obtaining Consent	Signature of Person Obtaining Consent	Date	Time AM PM

Blind or Illiterate Signature Section ***At the time of consent, also complete this section if consent is obtained from an individual who is unable to read and/or write but can otherwise communicate and/or comprehend English (e.g., blind, physically unable to write, etc.)***

Declaration of witness:
By signing below, I confirm I was present for the entire consent process. The method used for communication (e.g., verbal, written, etc.) with the subject was: _____ .

The specific means (e.g., verbal, written, etc.) by which the subject communicated agreement to participate was: _____.

Printed Name of Witness	*Signature of Witness*	*Date*	*Time AM PM*

Uso de un catéter de goma roja para facilitar una intubación nasotraqueal en pacientes adultos: Ensayo prospectivo, aleatorizado, controlado

Consentimiento para participar en un estudio de investigación que se llevará a cabo en
Parkland Health & Hospital System

Información acerca de este formulario

Es posible que usted sea elegible para participar en un estudio de investigación. Este formulario le brinda información importante sobre el estudio.

Tómese un momento para revisar detenidamente esta información. Debe hablar con los investigadores acerca del estudio y hacerles cualquier pregunta que pudiera tener. También es recomendable que hable con otras personas (por ejemplo, sus amigos, familiares o un médico) acerca de su participación en este estudio. Si decide participar en el estudio, se le pedirá que firme este formulario. Antes de firmar este formulario, asegúrese de comprender de qué se trata el estudio, incluidos los riesgos y los posibles beneficios para usted.

Informe a los investigadores o al personal del estudio si está participando en otro estudio de investigación.

Su médico es un investigador en este estudio. Está interesado tanto en su atención médica como en la realización de este estudio de investigación. Usted puede hablar en cualquier momento sobre su atención con otro médico que no forme parte de este estudio de investigación. No está obligado a participar en ningún estudio de investigación ofrecido por su médico.

Participación voluntaria: no está obligado a participar si no desea hacerlo. También puede retirarse del estudio en cualquier momento. Si decide dejar de participar en este estudio de investigación, eso no afectará su relación con el personal o los médicos de UT Southwestern. El hecho de que participe o no participe no tendrá ningún efecto en sus derechos legales ni en la calidad de su atención médica.

Si usted es estudiante de medicina, becario, docente o miembro del personal del Medical Center, su situación no se verá afectada de ningún modo.

Información general: "¿Quién lleva a cabo esta investigación?"

Investigador principal
El investigador principal (Principal Investigator, PI) es el investigador que dirige este estudio; el PI es responsable de proteger sus derechos, seguridad y bienestar como participante en la investigación. La PI de este estudio es la Dra. Christina Riccio del Departamento de Anestesiología y Manejo del Dolor de UT Southwestern Medical Center y Parkland Health Hospital System.

Propósito: "¿Por qué se realiza este estudio?"

La intubación nasal es la colocación de un tubo de respiración desde la nariz hasta la tráquea para brindar una vía respiratoria abierta para sus pulmones durante la anestesia. Este tipo de intubación se prefiere cuando el cirujano necesita acceso a la boca y la mandíbula.

Uso de cualquier fármaco o dispositivo en investigación
Este estudio implica el uso de un dispositivo en investigación llamado catéter de la uretra multiuso de Bard. "En investigación" significa que el dispositivo aún no ha sido aprobado por la Administración de Alimentos y Medicamentos (Food & Drug Administration, FDA) de los EE. UU. específicamente para guiar una intubación endotraqueal nasal, aunque es usado con frecuencia para este propósito por proveedores de anestesia.

Se le pide que participe en un estudio de investigación en manejo de las vías respiratorias que implica una intubación nasotraqueal. Por lo general, se realiza un intubación nasotraqueal colocando un tubo de respiración blando a través del conducto nasal hasta la tráquea. Hay varios métodos que el anestesiólogo puede usar para colocar este tubo. Sin embargo, la mayoría de los métodos pueden causar un sangrado nasal (epistaxis). Los investigadores compararán dos técnicas de intubación nasal, el método tradicional en comparación con la guía del tubo de goma roja, que se usan con más frecuencia en niños.

Los investigadores esperan saber qué técnica de intubación nasal causará menos sangrado nasal (epistaxis).

Habrá una descripción de este ensayo clínico disponible en http://www.ClinicalTrials.gov, tal como lo exige la ley de los EE. UU. Este sitio web no incluirá información que pueda identificarlo. Como máximo, en el sitio web se incluirá un resumen de los resultados. Puede realizar búsquedas en este sitio web en cualquier momento.

Información sobre los participantes del estudio: "¿Quién participa en esta investigación?"

Se le pide que participe en este estudio porque se está sometiendo a una cirugía que requiere la colocación de un tubo a través de su conducto nasal.

¿Cuántas personas se espera que participen en este estudio?
Este es un ensayo clínico multicéntrico. En este estudio se inscribirán aproximadamente 130 participantes del estudio. Solo 56 participantes en el estudio participarán en el Sistema Hospitalario de Parkland. Los 56 participantes restantes del estudio se inscribirán en el MD Anderson Center.

Información acerca de los procedimientos del estudio: "¿Qué se hará si decide participar en la investigación?"

Procedimientos de selección

- Examen físico: Se usarán los resultados del examen físico realizado como parte de su atención estándar.
- Si es capaz de quedar embarazada, también se le hará una prueba para la detección del embarazo como parte de su atención estándar antes de participar en el estudio.
- Su registro médico se revisará para determinar su elegibilidad para el estudio.

Los resultados de los exámenes, las pruebas y/o los procedimientos de selección serán examinados para determinar si se le permitirá continuar en el estudio. Si no se le permite continuar en el estudio, el investigador analizará los motivos con usted y le comentará otras opciones posibles.

Asignación a los grupos del estudio:
Cuando se determine que es elegible para el estudio, será asignado al azar (como cuando se lanza una moneda al aire) a uno de los grupos del estudio de intubación nasal, la técnica de intubación nasal tradicional frente a la intubación nasotraqueal con guía del tubo de goma roja.

- **La técnica de control (método tradicional):** Un tubo llamado tubo endotraqueal nasal se colocará a través de su conducto nasal hasta la parte posterior de la boca (orofaringe). El tubo nasotraqueal será guiado hasta la tráquea (vía respiratoria más grande) bajo visualización directa con un laringoscopio asistido con video, que esun pequeño dispositivo para observar su garganta y laringe.
- **Guía de tubo de goma roja:** Un tubo de goma roja blando se colocará en su nariz para guiar el tubo más largo a través de su conducto nasal hasta la parte posterior de la boca. El tubo nasotraqueal será guiado hasta la tráquea (vía respiratoria más grande) bajo visualización directa con un laringoscopio asistido con video. Esta técnica se utiliza con frecuencia en niños para disminuir traumatismos en su nariz.

No sabrá si usted está recibiendo el método tradicional o el método del tubo de goma roja para colocación de la vía respiratoria hasta su conducto nasal. Los investigadores sabrán qué método se usará.

Ambos procedimientos para la intubación nasal descritos se consideran el estándar de atención. En el método tradicional, un tubo endotraqueal nasal lubricado suavizado con agua caliente se coloca en la fosa nasal del paciente sin guía del tubo de goma roja. La guía del tubo de goma roja se usa con más frecuencia en niños y también es una opción de estándar de atención para su anestesiólogo.

Procedimientos del estudio: como participante, se le realizarán los siguientes procedimientos:

- Será asignado aleatoriamente a uno de los grupos del estudio. Ambas técnicas para la intubación nasotraqueal se consideran el estándar de atención. Ya sea que esté en el estudio o no, se someterá a una intubación endotraqueal nasal mediante uno de estos métodos. Se insertará un tubo a través de su fosa nasal hasta su tráquea (una vía respiratoria desde su nariz hasta su pulmón) para un manejo de las vías respiratorias durante la anestesia.
- El investigador evaluará la parte posterior de la boca para detectar cualquier signo de sangrado.
- Le pedirán que califique su dolor después de una cirugía en una escala de 1 a 10 (0=ningún dolor y 10=peor dolor imaginable). Su dolor se evaluará a los 30 y 60 minutos después de ingresar en la unidad de cuidados posteriores a la anestesia (post-anesthesia care unit, PACU).
- La gravedad del sangrado nasal se evaluará de inmediato después de una colocación del tubo endotraqueal nasal.
- Los riesgos del estudio se incluyen en la sección de riesgos. Se le monitoreará para detectar si experimenta efectos secundarios durante el período del estudio.

- Estará en el estudio durante la cirugía hasta el alta de la unidad de cuidados de la anestesia (PACU).

¿Podría su participación finalizar anticipadamente? Hay varios motivos por los cuales los investigadores pueden tener que dar por finalizada su participación en el estudio (retiro anticipado). Algunos de los motivos son:

- El investigador considera que permanecer en el estudio no es lo mejor para usted.
- Usted se vuelve no elegible para participar.
- Su afección cambia y usted necesita un tratamiento que no se permite mientras participa en el estudio.
- Usted no sigue las instrucciones de los investigadores.
- El estudio se interrumpe.

Los investigadores analizarán sus opciones de atención médica cuando finalice su participación en este estudio.

Riesgos: "¿Cuáles son los riesgos de participar en la investigación?"

Riesgos de la investigación
Los investigadores han designado este estudio para aprender cuán bien la intubación nasal con la guía de goma roja se compara con el método de intubación nasal tradicional. El grupo del tubo de goma roja puede no ser tan bueno como las técnicas tradicionales aceptadas con más frecuencia.

Riesgos de los procedimientos de investigación específicos
Existen riesgos por participar en este estudio de investigación. Un riesgo es que usted tenga efectos secundarios mientras participa en el estudio.

El riesgo de la técnica del tubo de goma roja:

- **Sangrado nasal (epistaxis).** Este es un efecto secundario frecuente de la intubación nasal. Los investigadores esperan menos sangrado nasal usando la guía del tubo de goma roja. Puede haber un riesgo de lesión mucosa y sangrado con la intubación nasotraqueal guiada con el tubo de goma roja. El lubricante con base de agua se usará para disminuir el riesgo de traumatismo nasal. Se prevé que este riesgo no es más alto que el de la intubación nasal estándar en adultos.

El riesgo de la técnica de intubación nasal tradicional:

- **Sangrado nasal.** Este es un efecto secundario frecuente de la intubación nasal. El lubricante con base de agua se usará para disminuir el traumatismo nasal.

Por lo general, los efectos secundarios de este estudio desaparecen poco después de la intubación nasal. En algunos casos, los efectos secundarios pueden ser duraderos o pueden causar un sangrado nasal reiterado.

A todas las personas que participen en el estudio se las observará detenidamente para detectar efectos secundarios. Sin embargo, los médicos del estudio no siempre conocen todos los efectos secundarios que pueden ocurrir. Asegúrese de informar de inmediato a su médico del estudio sobre cualquier efecto secundario que tenga mientras participa en el estudio.

En la siguiente sección se describirán los riesgos relacionados con su participación en este estudio de investigación. Debe hablar con su médico del estudio acerca de cualquier efecto secundario u otros problemas que tenga durante su participación en el estudio.

Para obtener más información sobre los riesgos y efectos secundarios, consulte a uno de los investigadores o al personal del estudio.

¿Existen riesgos relacionados con retirarse del estudio?
Si decide retirarse de este estudio anticipadamente, analice su decisión con la investigadora principal. La investigadora podrá solicitarle que complete los procedimientos de retiro del estudio.No hay ningún riesgo para usted si no completa los procedimientos de retiro finales y puede decidir no participar en ellos.

¿Existen riesgos si usted también participa en otros estudios de investigación?
Participar en más de un estudio de investigación simultáneamente puede aumentar los riesgos para usted. También puede afectar los resultados de los estudios. No debe participar en más de un estudio sin la aprobación de los investigadores.

Procedimientos o tratamiento alternativos: "¿Qué otras opciones existen a la participación en este estudio?"

Sus otras opciones pueden incluir la colocación de un tubo endotraqueal nasal lubricado termosuavizado en su fosa nasal sin la guía del tubo de goma roja.

Pagos: ¿Habrá algún pago por participar?

No hay ninguna compensación por participar en esta investigación

¿Qué sucede si se produce una lesión relacionada con la investigación?
Los investigadores han tomado medidas para minimizar los riesgos conocidos o previstos. Sin embargo, es posible que aun así usted presente problemas o efectos secundarios, aunque los investigadores sean cuidadosos para evitarlos. En caso de que se produzca una lesión relacionada con la investigación o si presenta una reacción adversa, comuníquese de inmediato con su médico del estudio. Consulte la sección "Información de contacto" para obtener los números de teléfono e información adicional. También es posible que tenga que informar a sus médicos habituales.

Si sufre una lesión o se enferma por participar en este estudio de investigación, se le proporcionará atención médica. Esta atención se le podrá facturar a usted o a su seguro. Dependiendo de las circunstancias, esta atención se le podría proporcionar sin costo para usted. No tenemos previsto darle dinero si se lesiona. La investigadora puede proporcionarle más información.

Si firma este formulario, usted no renuncia a sus derechos a solicitar compensación adicional si sufre un daño como consecuencia de participar en este estudio.

Beneficios: "¿Cómo podrían usted u otras personas beneficiarse de su participación en este estudio?"
El beneficio posible de participar en este estudio es una disminución de traumatismo nasal y sangrado nasal *que probablemente contribuya a su bienestar después de la cirugía*. No hay garantías ni promesas de que recibirá algún beneficio de este estudio.

Esperamos que la información obtenida a partir de este estudio beneficie a otras personas con afecciones similares en el futuro.

Costos: ¿Costará algo participar en este estudio?

Usted o su compañía de seguro médico será responsable del costo de los tratamiento y procedimientos que se realizarán ya sea que participe o no en este estudio, como por ejemplo intubación traqueal nasal con la técnica tradicional o usando la guía del tubo de goma roja o anestesia para cirugía. Es importante comprender que algunas compañías de seguro no cubren algunos costos (por ejemplo, fármacos aprobados que se usan de una manera diferente a las indicadas en el prospecto). Si su compañía de seguro no cubre estos tratamientos o procedimientos, usted deberá pagarlos. "Consulte con los investigadores si tiene alguna pregunta sobre cuánto le costará participar en este estudio (por ejemplo, facturas, honorarios u otros costos relacionados con la investigación)".

Confidencialidad: ¿Cómo se mantendrá la confidencialidad de sus registros?

La información que obtengamos sobre usted en este estudio se manejará de manera confidencial, dentro de los límites de la ley. Si publicamos los resultados del estudio en un libro o una revista científica, no la identificaremos. La Junta de Revisión Institucional y otros grupos que tienen la responsabilidad de supervisar la investigación pueden querer ver los registros del estudio que le identifican como sujeto en este estudio.

Sección de la Ley de Portabilidad y Responsabilidad del Seguro Médico (Health Insurance Portability and Accountability Act, HIPAA):
Las políticas de las investigaciones requieren que se proteja su información privada, y esto es especialmente válido para su información médica. Sin embargo, la ley a veces permite o exige que otras personas vean su información. La información mencionada abajo es una descripción del modo en que se protegerán su privacidad y la confidencialidad de sus registros de la investigación en este estudio. La información médica obtenida durante este estudio y los resultados de cualquier prueba o procedimiento que puedan afectar su atención médica podrán incluirse en su registro médico. La información incluida en su registro médico estará disponible para los proveedores de atención médica y las personas autorizadas, incluida su compañía de seguros.

¿Qué es la información médica protegida (Protected Health Information, PHI)?
La información médica protegida es la información acerca de la salud de una persona que incluye información que podría permitir identificar a quién pertenece. Conforme a la ley, usted tiene derecho a decidir quién puede ver su información médica protegida. Si decide participar en este estudio, estará otorgando su permiso a los investigadores y al personal del estudio de investigación (las personas que llevan a cabo el estudio) para que vean y usen la información médica sobre usted para este estudio de investigación. Al llevar a cabo esta investigación, la información médica sobre usted que analizaremos y usaremos incluirá lo siguiente:

Sus antecedentes médicos, la información que obtengamos de su registro médico, la información incluida en sus registros médicos subyacentes relacionados con sus antecedentes médicos y los tratamientos anteriores al estudio, información que se crea o recopila durante su participación en el estudio, incluidos los antecedentes médicos y de tratamiento que incluyen sangrado nasal, información relacionada con la intubación, cualquier evento adverso durante la intubación y cirugía, agente anestésico utilizado para anestesia general, concentración de oxígeno y dióxido de carbono en el tubo endotráqueal e información que nos brinde durante su participación en el estudio, tal como información demográfica como su edad, y puntaje de dolor.

Obtendremos esta información preguntándoles a usted y a su médico, y a través de su historia clínica en Parkland Hospital.

¿Cómo se compartirá su PHI?
Puesto que este es un estudio de investigación, no podremos mantener la absoluta confidencialidad de su PHI. Es posible que compartamos su información médica con personas y grupos involucrados en la supervisión de este estudio de investigación, entre los que se incluyen los siguientes:

- Los siguientes colaboradores en otras instituciones que están involucradas en el estudio: Parkland Health Hospital System.
- Los integrantes del equipo local de investigación.
- La Junta de Revisión Institucional, la Oficina del Programa de Protección de la Investigación en Seres Humanos (Human Research Protection Program Office) y la Oficina de Cumplimiento (Compliance Office) de University of Texas Southwestern Medical Center, y otros grupos que supervisan de qué manera se llevan a cabo los estudios de investigación.
- Las oficinas de investigación de University of Texas Southwestern Medical Center Parkland Health y Hospital System.
- La Administración de Medicamentos y Alimentos (FDA) y otros organismos reguladores gubernamentales de EE. UU. e internacionales encargados de supervisar la investigación de fármacos o dispositivos.
- Representantes de organismos gubernamentales y reguladores nacionales y extranjeros pueden recibir permiso de acceso directo a su información médica para supervisar, llevar a cabo actividades de cumplimiento y determinar la aprobación de nuevos medicamentos, dispositivos o procedimientos.

Si decide participar en este estudio, estará dando su permiso para que los grupos mencionados anteriormente recopilen, usen y compartan su información médica. En caso de que decida no permitir que estos grupos recopilen, usen y compartan su información médica como se explicó anteriormente, no podrá participar en el estudio de investigación.
Algunas partes de su PHI pueden ser fotocopiadas y enviadas a una ubicación central o transmitidas de forma electrónica, a través del correo electrónico o del fax, por ejemplo. Es posible que los grupos que reciban su información médica no estén obligados a mantener su privacidad. Pueden pasarles información a otros grupos o personas que no estén mencionados aquí.

¿Cómo se protegerá su PHI?
En un esfuerzo por proteger su privacidad, el personal del estudio utilizará números de código, en lugar de su nombre, para identificar su información médica. Se utilizarán iniciales y números en cualquier fotocopia de sus registros del estudio y en otros materiales del estudio que contengan información médica que se envíen fuera de Parkland Hospital para su revisión o análisis. Si los resultados de este estudio se presentan en revistas médicas o en congresos, no se le identificará.

¿Está obligado a permitir el uso de su información médica?
Usted no está obligado a permitir (autorizar) que los investigadores y otros grupos vean y compartan su información médica. Si decide no permitir que los investigadores y otros grupos usen su información médica no habrá sanciones, pero no se le permitirá participar en el estudio.

Después de inscribirse en este estudio, podrá pedir a los investigadores que dejen de usar su información médica en cualquier momento. Sin embargo, debe establecerlo por escrito y enviar su carta a la Dra. **Christina Riccio** a Department of Anesthesiology and Pain Management at UT Southwestern Medical Center (5323 Harry Hines Blvd, Dallas, TX, 75390-9068). Si pide a los investigadores que dejen de usar su información médica, su participación en el estudio finalizará y el personal del estudio dejará de recopilar información médica nueva de usted y sobre usted para este estudio. Sin embargo, el personal del estudio continuará usando la información médica recopilada hasta el momento en que reciba su carta con el pedido de que deje de hacerlo.

¿Puede solicitar ver la PHI que se recopila sobre usted para este estudio?
Las normas federales establecen que puede ver la información médica que recopilamos sobre usted y que usamos en este estudio. Comuníquese con el personal del estudio si necesita revisar su PHI recopilada para este estudio.

Debido al tipo de investigación, solamente podrá acceder a su PHI cuando el estudio haya finalizado. En ese momento, tendrá derecho a ver y a copiar la información médica que recopilemos sobre usted durante el estudio, mientras el personal del estudio y los demás grupos involucrados conserven esa información.

¿Durante cuánto tiempo se usará su PHI?
Al firmar este formulario, usted acepta permitirnos usar y divulgar su información médica para los propósitos del estudio hasta el final del estudio. Este permiso para usar su información médica personal vence cuando finaliza la investigación y se completa toda la supervisión del estudio requerida.

Información de contacto: ¿Con quién se puede comunicar si tiene preguntas, inquietudes, comentarios o quejas?

Si tiene preguntas ahora, no dude en hacerlas. Si más adelante tiene otras preguntas, inquietudes, comentarios o quejas, o si desea informar un problema que podría estar relacionado con este estudio, comuníquese con el siguiente contacto: Dra. **Christina Riccio** a Department of Anesthesiology and Pain Management at UT Southwestern Medical Center (5323 Harry Hines Blvd, Dallas, TX, 75390-9068).

Para usar el buscapersonas, tiene que tener un teléfono con teclado de tonos (teléfono de botones). Marque el número del buscapersonas como marcaría cualquier número de teléfono. Cuando oiga 3 pitidos cortos y agudos, marque el número al cual quiere que la médica le devuelva la llamada. Presione el botón #, cuelgue y espere a que la médica le devuelva la llamada.
Contacto principal:
La Dra. Christina Riccio puede ser contactada llamando al 469-419-8446 durante el horario de atención habitual y al 214-786-3541 en cualquier momento.
Si el contacto principal no está disponible, comuníquese con
El Dr. David Mercier que puede ser contactado llamando al 214-786-0313.

El Programa de Protección de la Investigación en Seres Humanos (Human Research Protection Program, HRPP) del University of Texas Southwestern Medical Center supervisa la investigación en sujetos humanos. Representantes del HRPP y de la Junta de Revisión Institucional (Institutional Review Board, IRB) responderán cualquier pregunta acerca de sus derechos como sujeto de investigación y recibirán cualquier inquietud, comentario o queja que usted pueda tener. Puede comunicarse con el HRPP si llama a la oficina al 214-648-3060.

Sección de firmas para la autorización y el consentimiento de la investigación

Si acepta participar en esta investigación y acepta el uso de su información médica protegida en esta investigación, firme esta sección. Se le entregará una copia de este formulario como constancia. Al firmar este formulario, no renuncia a ninguno de sus derechos legales.

FIRME ESTE FORMULARIO SOLO SI LOS SIGUIENTES ENUNCIADOS SON VERDADEROS:

- Ha leído (o le han leído) la información suministrada previamente.
- Sus preguntas acerca de la investigación y acerca de la recopilación, del uso y de la divulgación de su información médica protegida han sido respondidas a su satisfacción.
- Usted ha decidido libremente participar en esta investigación o da voluntariamente su consentimiento para que otra persona participe en este estudio porque cree que esa persona desearía participar si fuera capaz de tomar la decisión y usted cree que es lo mejor para esa persona.
- Comprende que una copia de este formulario de consentimiento informado firmado, la información sobre este estudio y los resultados de cualquier prueba o procedimiento que pudieran afectar su atención médica pueden ser incluidos en su registro médico. La información incluida en su registro médico estará disponible para los proveedores de atención médica y las personas autorizadas, incluida su compañía de seguros.
- Usted autoriza la recopilación, el uso y la divulgación de su información médica protegida (la información médica protegida de otra persona) tal como se describe en este formulario.

Sección de firmas para adultos

			a. m. p. m.
Nombre del participante, en letra de imprenta	Firma del participante	Fecha	Hora
			a. m. p. m.
Nombre de la persona que obtiene el consentimiento, en letra de imprenta	Firma de la persona que obtiene el consentimiento	Fecha	Hora

<u>Sección de firma para personas ciegas o analfabetas</u> En el momento del consentimiento, también complete esta sección si se obtiene el consentimiento de una persona que no puede leer y/o escribir pero se puede comunicar en español y/o comprenderlo de otro modo (p. ej., ciego, físicamente incapaz de escribir, etc.)

Declaración del testigo:
Al firmar a continuación, confirmo que estuve presente durante todo el proceso de consentimiento.
El método usado para la comunicación con el sujeto (p. ej., verbal, escrito, etc.) fue: .

El medio específico (p. ej., verbal, escrito, etc.) mediante el cual el sujeto comunicó su acuerdo para participar fue: _____.

			a. m. ***p. m.***
Nombre del testigo, en letra de imprenta	***Firma del testigo***	***Fecha***	***Hora***