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Tegarderm® Placement for Bag Mask Ventilation in the Bearded Patient

Study Protocol
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PROTOCOL TITLE:

Tegaderm™ Placement for Bag Mask Ventilation in the Bearded Patient

PRINCIPAL INVESTIGATOR:

Neal Gerstein, MD
Anesthesiology & Critical Care Medicine
272-2610
ngerstein@salud.unm.edu

ADMINISTRATIVE CONTACT:

Tim Petersen, PhD
Anesthesiology & Critical Care Medicine
272-1762
timpetersen@salud.unm.edu

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REGULATORY FRAMEWORK:

Please indicate all that apply:

☐	DOD (Department of Defense)
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☐	DOJ (Department of Justice)
☐	ED (Department of Education)
☐	EPA (Environmental Protection Agency)
☒	FDA (Food and Drug Administration)
☒	HHS (Department of Health and Human Services)
☐	VA
☐	Other:

FUNDING: Departmental sources only

CLINICAL TRIALS

Is this a clinical trial per the NIH definition of a Clinical Trial? ☒ Yes ☐ No

NIH Definition of a Clinical Trial:

A research study in which one or more human subjects are prospectively assigned to one or more interventions. An "intervention" is defined as a manipulation of the subject or subject's environment for the purpose of modifying one or more health-related biomedical or behavioral processes and/or endpoints. Examples include: drugs/small

molecules/compounds; biologics; devices; procedures (e.g., surgical techniques); delivery systems (e.g., telemedicine, face-to-face interviews); strategies to change health-related behavior (e.g., diet, cognitive therapy, exercise, development of new habits); treatment strategies; prevention strategies; and, diagnostic strategies (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.

Use the following four questions to determine the difference between a clinical study and a clinical trial:

1) Does the study involve human participants? ☒ Yes ☐ No
2) Are the participants prospectively assigned to an intervention? ☒ Yes ☐ No
3) Is the study designed to evaluate the effect of the intervention on the participants? ☒ Yes ☐ No
4) Is the effect being evaluated a health-related biomedical or behavioral outcome? ☒ Yes ☐ No

Note that if the answers to the 4 questions are yes, your study meets the NIH definition of a clinical trial, even if…

- You are studying healthy participants
- Your study does not have a comparison group (e.g., placebo or control)
- Your study is only designed to assess the pharmacokinetics, safety, and/or maximum tolerated dose of an investigational drug
- Your study is utilizing a behavioral intervention

If yes to all 4 questions, please confirm that the research team is familiar with and agrees to comply with the investigator requirement to register the study on the ClinicalTrials.gov database. Additionally, the approved consent document(s) must be uploaded to the ClinicalTrials.gov database ☒ Yes ☐ No

For any assistance with registration of your trial or the requirements, please contact HSC-CTSCResearchConcierge@salud.unm.edu

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1. Objectives

1.1. This is a prospective randomized cross-over controlled trial intended to assess the efficacy of applying Tegaderm™ over bearded patients' circumoral area to improve bag mask ventilation after induction of general anesthesia. We will use Pneumotachography to measure our primary outcome: the amount of airway leak during mask ventilation (Tidal Volume Inspired mL –Tidal Volume Expired mL). Secondary measures include peak inspiratory pressures (PP_{ins}; cm H_2O) and airway resistance (Res; cm H2O/l/sec).

1.2. Hypothesis: Application of Tegaderm™ over patient with circumoral facial hair will significantly improve bag mask ventilation via improvement of facemask seal.

2. Background

2.1. Bag mask ventilation (BMV) is an essential skill for health care professionals involved in airway management. This ubiquitously needed skill can be lifesaving in emergent situations but is frequently impeded by various patient characteristics. If incorrectly approached and applied, BMV may be ineffective and lead to hypoxia, hypercarbia [1] or pulmonary aspiration [2]. Difficult mask ventilation (DMV) pathophysiology is well described by El-Orbany et al as having two broad components: 1) operator or technique related and 2) airway related factors. Independent risk factors for DMV include the presence of a beard, increased BMI (> 26 kg/m2), edentulism, age >55 years, history of snoring, Mallampati III or IV, male gender, limited mandibular protrusion, and airway masses [1,3–5]. In recent years, there has been a joint effort amongst emergency physicians, anesthesiologists, and pre-hospital clinicians to improve our understanding of BMV, standardize our approach and teach optimization with a surplus of corrective measures when faced with difficult BMV [6–11]. The most basic optimizing maneuvers such as switching from a single hand to two-handed thenar-eminence grip has shown promising objective results [12,13]. More novel approaches to improve facemask seal have been suggested such as keeping dentures in mouth or packing the mouth with gauze during induction of general anesthesia of the edentulous patient [14], and employing ergonomically designed facemasks [15], accessories [16], and intraoral masks [17,18] to reduce operator error and grip fatigue.

A common independent DMV risk factor encountered by multiple modalities of healthcare providers is the bearded airway. Bag mask ventilation in the bearded patient has many difficulties to overcome, for both the novice and expert alike. In a review of 50,000 anesthetics looking at prediction of impossible mask ventilation, the bearded patient was deemed the only modifiable independent predictor despite attempts by multiple anesthesiologists [19]. There are multiple factors that contribute to beards as an independent risk factor for DMV. The presence of a beard decreases the ability to create an airtight seal of the face mask increasing air leakage during positive pressure ventilation by providers [19,20]. Beards can also conceal architectural facial anomalies concealing other risk factors for DMV, such as men with retrolithic jaws in attempt to alter their appearance [21].

Additionally, beards can inhibit the provider's ability to effectively grip the jaw to perform an adequate chin lift [22].

2.2. There have been multiple proposed techniques to address the management of beards. The most effective, but perhaps hardest to achieve, is shaving of the beard prior to induction [3]. For a willing patient in a non-emergent setting this may be the most ideal intervention, but has limited compliance, and is not applicable in emergent or pre-hospital settings where time is more crucial and resources more limited. Viscous jelly to form an adequate seal at the mask-beard-skin interface has been proposed [23], but may further limit effective grip to perform chin lift. Use of a pediatric mask over the nose and nasopharyngeal airway with manual closure of the oral airway [24], which has shown promising data in maintaining upper airway patency but may not be readily translatable across multiple provider modalities. The use of cling film to wrap the face in an emergent scenario [25], previously noted to require significant head manipulation, potential risk for pulmonary edema, and limiting gas exchange during the intervention [26]. The use of a supraglottic airway device may also be an appropriate intervention for DMV bearded patients, but there is limited evidence in the literature to say LMA is superior to face masks in the setting of difficult airways and a supraglottic airway is commonly an inappropriate airway device in the perioperative period [6,27–29].

2.3. A simple novel approach noted improvement of BMV in the bearded patient [30,31] by placing a large (6 x 8 inch) Tegaderm™ across the lower face to improve face-to-mask seal, after first cutting a hole in the device to permit passage of air and instruments. To date, evidence for improved facemask seal in the bearded patient has only been anecdotal. We plan on studying a heretofore non-studied technique involving application of a large Tegaderm™ across the lower face of the bearded patient to quantify its effectiveness at improving mask ventilation in this anesthetized population. This technique can be applied rapidly, without dramatic head manipulation, preserving effective grip, and can be adopted across multiple healthcare modalities, making it a worthy intervention to explore in detail. By quantifying the effectiveness of this intervention, we hope this study can be used to inform guidelines for the management of difficult BMV in the bearded patient.

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3. Study Design

3.1. Our study design is a randomized prospective crossover trial in adult patients (>18 years), with circumferential perioral facial hair longer than 5 mm who will undergo elective non-cardiac surgery in the main adult operating rooms of the University of New Mexico Hospital.

3.2. Allocation concealment: Providers and subjects will be blinded to which method they will start with (control versus intervention) via envelope method prior to induction of general anesthesia.

3.3. Subjects who are consented to participate in the study will have facial hair measured as a continuous variable length (mm).

3.4. Mask ventilation operators will be confined to anesthesiology residents, anesthesiologist assistants (AA), and AA students all of whom are familiar with bag mask ventilation. Mask ventilation will occur using a two-handed Thenar-Eminence (TE) grip without the addition of an oropharyngeal airway. All operators will be instructed on how to perform this technique prior to patient enrollment. We will use Pressure Control ventilation mode on Anesthesia Ventilator machine (Dräger Perseus A500) set at 10 breaths per minute, I:E time of 1:2 and peak inspiratory pressure of 20 cm H_2O, all of which are routine in our practice and within typical ranges at the national level. These are specified only in order to reduce practice variation not related to the intervention itself. An external pneumotachograph device and sensors (Phillips Respironics NM3™ respiratory profile monitor; Respironics CAPNOSTAT® Mainstream CO2 sensor) will be used to measure ventilation parameters (Vt_{ins}; mL, Vt_{Exp}; mL, PP_{ins}; cm H_2O, Res; cm H_2O/L/sec) with collected data electronically saved to a dedicated flash drive associated with the pneumotachograph .

4. Inclusion and Exclusion Criteria

4.1. A study investigator will screen patients with facial hair on the day of surgery in the preoperative holding area. We will enroll patients on the day of surgery and have them sign an informed written consent to participate in the study.

4.2. Inclusion criteria

- Adult patients with perioral facial hair greater than 5 mm in length, and undergoing elective non-cardiac surgery inclusive of BMV.

4.3. Exclusion criteria are listed below. The exclusion criterion relating to known Tegaderm allergy will be screened for during verbal communication between the patient/participant and his/her doctor (who is also an investigator). All other exclusion criteria draw on information that is part of the routine pre-anesthesia assessment conducted for patients having general anesthesia.

- known allergy to Tegaderm product and/or its adhesive
- emergency surgery
- active or unstable cardiac disease
- ASA physical status* ≥ 4. ASA 4 physical status is a patient with severe systemic illness that is a constant threat to life; higher numbers indicate more severe morbidity.

  *ASA or American Society of Anesthesiologists physical status is a subjective designation by anesthesiologists used to describe allotted anesthetic and surgical risk to a patient undergoing an anesthetic based on the patients predetermined risk factors, disease burden and acute or life threatening pathology)
- external or internal active airway obstruction from tumor, abscess, or laryngeal edema,
- organic or non-organic oropharyngeal anatomical defects including history of neck radiation
- moderate to severe acute and chronic restrictive or obstructive lung diseases (including chronic obstructive pulmonary disease and asthma
- patients that require rapid sequence intubation or with aspiration risk
- cervical spine injury, previously documented difficult mask ventilation or intubation
- BMI≥50
- Vulnerable populations: Children, prisoners, pregnant patients, cognitively impaired adults

5. Number of Subjects

5.1. This is a single-site study.

5.2. The data that would be required for a formal sample-size calculation with a reliable power estimate are not available. For this reason, this study will use a 2-phase enrollment study plan with an initial 25-patient external pilot to inform the sample size calculation for the main phase. The investigators will submit a modification to HRRC with the planned sample size for the main phase upon completion of the

external pilot. However, the investigators may begin enrolling main-phase patients immediately upon completion of the external pilot in order to maintain study momentum. The investigators will not enroll more than 25 main-phase patients before receiving HRRC authorization for the modification with the updated sample size.

5.3. The investigators are therefore requesting initial authorization to enroll up to 50 patients, with the expectation that a modification will be submitted to finalize the sample size. These additional participants (i.e. participants 26-50) are intended to allow the investigators to transition from the external pilot to the main phase while the modification for the final sample size is under consideration by HRRC.

6. Study Timelines

6.1. Describe time expectations:

Individual patients' participation will last less than five minutes.

Investigators anticipate that 12 to 18 months will be sufficient to enroll the planned 2-phase sample size.

Study completion (analysis and preparation of manuscripts and other presentations) is expected to take approximately 12 months after enrollment is completed.

7. Study Endpoints

7.1. *Describe the primary and secondary study endpoints.*

Primary outcome: Mask leakage, defined as the difference between average inspired and expired tidal volumes, as a percentage of inspired volume. Patients will serve as their own controls; the comparison is of the difference in leakage in the Tegaderm™ versus baseline conditions.

Secondary outcomes: 1. Difference in airway resistance between Tegaderm™ and baseline conditions, 2. Difference in peak inspiratory pressure between Tegaderm™ and baseline conditions, 3. Extent to which mask leakage change with Tegaderm™ depends on beard length.

7.2. *Describe any primary or secondary safety endpoints.*

If bag/mask ventilation is difficult and a Tegaderm™ not already in place, one will be placed in an effort to provide a better seal for the mask. If ventilation continues to be difficult, an Attending Anesthesiologist would attempt bag mask ventilation, consider placing an oral airway, and follow the difficult airway algorithm (6) by using supraglottic airway as a rescue device if deemed necessary. This event will be considered data and included in analyses.

8. Research Setting

8.1. *Describe the sites or locations where your research team will conduct the research.*

The research will be conducted in the main surgical suites of UNM Hospital.

8.2. *Identify where your research team will identify and recruit potential subjects.*

Potential subjects will be identified and recruited from investigators' regular patients at the UNM surgical suites, in pre-operative holding areas.

8.3. *Identify where research procedures will be performed including any laboratory analytics*

All research will occur in the UNM surgical suites.

9. Resources Available

9.1. *Investigator qualifications:*

PI Neal Gerstein MD is a board-certified anesthesiologist, Division Chief of Cardiac Anesthesiology and Professor at UNM. Other investigators include experienced clinicians, a PhD research specialist, and medical residents; all investigators' research duties are well within their usual job duties. All research procedures will be performed by personnel who have appropriate training, experience, and authorization.

9.2. *Medical decision-makers:*

All clinical decisions will be made by appropriate providers who are duly authorized and credentialed to do so.

9.3. *Other resources:*

- UNM's operating rooms handle a high caseload, and the investigators anticipate little difficulty in recruiting 60 relevant patients from among them in one calendar year.
- Engagement in research activities is an expected part of all investigators' job duties, so conducting this study is not anticipated to conflict with their clinical, scientific, or administrative duties.
- The UNM surgical suites are equipped with the personnel, supplies, and equipment necessary to respond to any eventuality that may arise as a result of participation in this study.

10. Prior Approvals

10.1. The completed Departmental Review Form is included with the initial application for review of this protocol

10.2. This study does not involve ionizing radiation, biological specimens, or specific medications.

11. Multi-Site Research

11.1. This is not a multi-site study.

12. Study Procedures

12.1. *Provide a thorough description of all study procedures, assessments and subject activities in a logical and sequential format.*

After obtaining informed written consent, patients will be pre-medicated with 1–2 mg of midazolam prior to entry into the operating room. Subjects will be transferred to the operating room table where they will lie in the supine position with the head and neck placed in the sniffing position. Mask ventilation operators will be confined to anesthesiology residents, Clinical anesthesiologist assistants (C-AA), and C-AA students all of whom are familiar with bag mask ventilation. Mask ventilation will occur using a two-handed Thenar-Eminence (TE) grip without the addition of an oropharyngeal airway. All operators will be instructed on how to perform this technique prior to patient enrollment. We will use Pressure Control ventilation mode on Anesthesia Ventilator machine (Dräger Perseus A500) set at 10 breathes per minute, I:E time of 1:2 and peak inspiratory pressure of 20 Cm H2O. An external pneumotachograph device and sensors (Phillips Respironics NM3™ respiratory profile monitor; Respironics CAPNOSTAT® Mainstream CO2 sensor) (figure1) will be used to measure ventilation parameters (Vt_{ins}; ml, Vt_{Exp}; ml, PP_{ins}; cm H_2O, Res; cm H_2O/L/sec) with collected data electronically saved to a dedicated flash drive associated with the pneumotachograph.

Prior to induction airway operators (Clinical Anesthesiologist Assistants, Anesthesiology Residents or Anesthesiologist attendings) will be trained to create an opening in the Tegaderm™. The steps of Tegaderm™ modification are as follows: 1.) Tegaderm™ will be folded in half. 2.) Two 1" cuts will be made forming an Isosceles triangle. 3.) Tegaderm™ is opened up, placed on the patient with the adhesive side down. Once placed the covering's structural backing is removed so not to create any creases, leaving a diamond shaped mouth hole allowing face mask perimeter to make contact with Tegaderm™.

1.)  2.)  3.) 

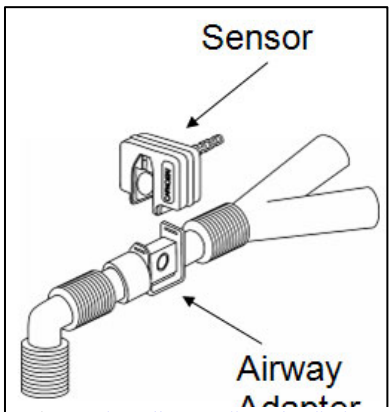

Figure 1: https://www.zoll.com/medical-products/defibrillators/r-series/etco2/

Once standard ASA monitors are applied, an adult-sized oxygen mask (Medline™ Anesthesia Mask) will be placed over patient's face for pre-oxygenation with 100% O2 at a rate of 10 liters/minute until measured expired oxygen ≥80%. Immediately prior to administration of induction medications we will open the randomization envelope denoting which technique we will apply first. General anesthesia will be induced with 1–3 mcg/kg bolus of fentanyl, 1.5 mg/kg of lidocaine, 2–3 mg/kg propofol and 0.6-1mg/kg Rocuronium for ideal mask ventilation conditions. The study interval will be specified as the period beginning with apnea, anesthesia induction with neuromuscular

blockade to completion of one minute of mask ventilation with and without Tegaderm™ use. Patients will act as their own controls. Anesthesia induction and apnea will be defined as no voluntary respiratory effort and the absence of the eyelid reflex. Complete Neuromuscular blockade will be defined as Train of Four Ratio of **0/4** with neuromuscular monitoring at the *Corrugator Supercilii* muscle.

Once subjects are apneic and induced, **3** mask ventilation breaths will be administered in order to 'acclimate' the user to the mask and insure a proper thenar-eminence (TE) grip is being used. The randomized crossover trial will be started once complete neuromuscular blockade is verified. Every consecutive trial will alternate between starting with Tegaderm™ use and no alteration with patients acting as their own controls. Both no alteration and Tegaderm™ portion of exam will use the Respironics NM3 ™ (Respironics Deutschland, Herrsching, Germany) and CAPNOSTAT® 5 (Phillips Healthcare corporation, Eindhoven, The Netherlands) sensors to measure primary outcomes: Inspired tidal volumes (Vt_{ins}; ml), expired Tidal Volumes of End Tidal CO2 (Vt_{Exp}; ml) which will be used to determine predefined adequate BMV (Inspired Tidal Volume- Expired Tidal Volume difference of <15% defined as adequate) and secondary outcomes: within-patient differences between Tegaderm™ and no-alteration conditions for peak inspiratory pressures (PP_{ins}; cm H_2O) and airway resistance (Res; cm H_2O/l/sec) for 60 seconds, and facial hair grouping comparisons. The anesthesia machine will be set to deliver standardized pressure-controlled ventilation using common parameters: peak inspiratory pressure of 20 cm H_2O, 10 breaths per minute, and an inspiratory-expiratory ratio of 1:2. These values are within common ranges used in standard practice, but may be modified during surgery as determined to be clinically appropriate by the attending anesthesiologist. General anesthesia will be maintained with sevoflurane 4-6% with 100% O_2 at a rate of 6 liters per minute. Once data is gathered for the first part of the trial (no alteration or Tegaderm™), we will change our technique and collect data for second 60 seconds component of the trial in similar fashion to initial data collection.

If during the "no alteration" portion of the study we fail to establish a seal after 3 attempts at ventilation, an Attending Anesthesiologist would assess the stability of the patient and, if needed, attempt bag mask ventilation, incorporate airway adjuncts, and follow the difficult airway algorithm. If the patient is deemed stable a Tegaderm™ will be immediately applied over the patient's face with a hole over the mouth. The same operator will perform TE grip MV technique in order to establish a seal and to collect our data. If a subject could not be rescue ventilated after application of Tegaderm™ placement, an Attending Anesthesiologist would follow the same rescue techniques as described above. Once the mask ventilation trial is completed, subjects will be intubated and maintained under general anesthesia as usual for their anticipated surgery.

In a hemodynamically unstable event the protocol will be halted in order to address the medical needs of the patient, the Attending Anesthesiologist would treat the event accordingly with the appropriate pharmacologic interventions. Once the patient is deemed medically stable the Attending Anesthesiologist would make the decision to

abort or proceed with the protocol. In the event of a cardiac event or equivalent the protocol will be aborted and the patient will be excluded from the trial.

12.2. Study data will be derived from the research interaction with the patient, and the electronic medical record (EMR). These data will be recorded on a data collection form that will be deidentified and associated with a unique study code. Data to be collected are as follows.

12.2..1. Patient background information

12.2..1.1. Past medical history

12.2..1.2. Surgery Type

12.2..1.3. Race

12.2..1.4. Obstructive Sleep Apnea History

12.2..1.5. Mallampati score

12.2..1.6. Age

12.2..1.7. Weight

12.2..1.8. Height

12.2..1.9. Body Mass Index

12.2..2. Study information

12.2..2.1. Level of the provider

12.2..2.2. Paralytic

12.2..2.3. Beard length (perioral)

12.2..2.4. Randomization result

12.2..2.5. Respiratory parameters

13.Data Analysis

13.1. *Describe the data analysis plan, including any statistical procedures.*

Paired data (within patient differences in leakage, PP_{ins}, and airway resistance) will be assessed with paired t-test or Wilcoxon rank-sum test, depending on distribution normality. Beard condition groups will be compared on the primary outcome (leakage difference > 15% significant) with ANOVA or Kruskal-Wallis test, also depending on distribution normality. Sensitivity analysis will provide percentage of observed standard deviation for detection of leakage difference and a traditional power analysis to provide the sample size required to detect significant outcome with our intervention.

13.2. *Provide a power analysis, if applicable*

The data and statistics that would be required for a formal sample-size calculation with a reliable power estimate are not available. For that reason, the investigators plan a 2-phase process. In the first (external pilot) phase, the investigators plan to enroll 25 participants following a published guideline (Whitehead AL, et al. *Statistical Methods in Medical Research* 2016; 25:1057-73) and use the generated data to obtain effect-size and standard deviation information. Those statistics will permit a valid sample size calculation for the second phase, i.e. the main trial. The investigators will submit a modification to HRRC with sample size justification for the main trial prior to enrolling any patients for it.

14. Provisions to Monitor the Data to Ensure the Safety of Subjects

This section is required when research involves more than Minimal Risk to subjects. Describe:

14.1. The PI will perform data and safety monitoring every 2 months, but the PI works closely with all study team members and will be kept apprised of study progress, including any adverse events.

14.2. The PI will review the collected data and the Electronic Anesthesia Record which already includes relevant safety outcomes and patient participant EMR. Relevant data includes oxygenation and ventilation parameters, airway pressures, and other information relevant to airway management. The data will be reviewed for desaturation events, elevated airway pressures, and any other adverse clinical outcomes related to airway management during the study. Any such adverse events would be immediately apparent in the stated records. The PI will obtain statistical advice as appropriate, but adverse events are expected to be sufficiently uncommon that they are likely to be addressed on a case-by-case basis.

14.3. The PI will refer to the EMR as appropriate to obtain relevant context on any adverse events.

14.4. Mask ventilations are routine prior to intubation and safety profiles are well established. It is not anticipated that the medical literature will report new findings that call the safety of this study into question.

14.5. The PI will review the incidence of adverse events related to Tegaderm™ use in this study to determine whether they exceed the incidence that would be expected without the use of the intervention. If, in the PI's opinion, adverse events occur and are related to the study, the PI will suspend the study and notify HRRC as noted in 14.6 below.

14.6. In accordance with HRRC policy, the PI will suspend the study in the event of any adverse outcome that is both significant and likely due to the procedure under investigation, in the PI's opinion, and report the event to HRRC for its review and subsequent recommendation.

14.7. The PI will notify HRRC in the event of study termination under 14.6 above.

15. Withdrawal of Subjects

15.1. The investigators have not identified any likely circumstances under which subjects may be withdrawn without their consent, as most study procedures occur after induction of general anesthesia. However, a patient who is unable to follow instructions after consent but before anesthesia induction may be withdrawn without their consent.

15.2. This study does not involve procedures or treatments that would require orderly termination plans. The interim between consent and commencement of study procedures is brief, which makes voluntary patient withdrawal before surgery unlikely. The investigators also believe that voluntary patient withdrawal after surgery is also unlikely, because all study procedures will have been completed by that point. In the unlikely event of a post-surgery withdrawal, the data collected on that patient will not be analyzed, but the patient's entry into the study will be recorded and reported as usual.

15.3. The investigators have not identified any circumstances for partial withdrawal.

15.4. The consent document contains information about withdrawal procedures and limitations.

16. Data Management/Confidentiality

16.1. Most members of the research team are physicians who interact with these and similarly-situated patients on a daily basis.

16.2. The research does require the use of direct identifiers (e.g. MRN) in order to accurately obtain complication data and link it to procedural data.

16.3. The research requires the use of Private Health Information (PHI), but the investigators will not disclose any identifiable information except as required by law.

16.4. The data do not include information that is typically considered to be sensitive, such as HIV status, substance abuse, or criminal behavior.

16.5. The investigators do not plan to pursue a Certificate of Confidentiality.

16.6. All investigators have completed routine UNM Health Sciences Center (HSC) training on the secure management and use of patient data. Identifiable data on paper forms will be maintained in a locked cabinet in a study team member's Anesthesiology Department office, which is a patient-restricted area; and in electronic format will be stored on HSC secure servers, which are password-protected.

16.7. Data will be deidentified upon completion of data collection and entry into a spreadsheet stored on UNM HSC secure servers, but will be identifiable (via a linking document containing study ID numbers and MRNs) until that point in order to permit accurate linkage of procedural and outcome data.

16.8. Any questionable entries in the paper data sheets will be verified by reference to the EMR, as appropriate.

16.9. Identifiable data will not be transmitted to outside entities, except as required by law.

16.10. Identifiable data will not be collected or transported by the internet; only on UNM HSC secure servers.

16.11. Study records will be maintained for 3 years after closure as required by federal regulations.

16.12. Recordings of audio/video will not be used. Any photographs obtained will be deidentified.

16.13. Data from this trial will not be shared with an external institution.

17. Data and Specimen Banking

17.1. Identifiable data will not be banked. Deidentified data will be maintained as part of routine study records for 3 years after closure, as noted in §16.11 above.

18. Risks to Subjects

18.1. The only identified risks are of allergy to the Tegaderm™ adhesive, which is rare; and mild irritation, which is uncommon. The risk of bag mask ventilation causing aspiration of stomach contents and barotrauma are theoretical and highly unlikely in this study population. The risk of these events occurring do not increase with our protocol (addition of 2 minutes of bag mask ventilation) versus an elective general anesthetic as we have excluded all patients that would incur this added risk. All research involves risks of loss of confidentiality, inconvenience, stress, and emotional upset.

18.2. The risk of allergic reaction is mitigated by performance of study procedures in UNMH operating rooms, which are furnished with the personnel, facilities, equipment, and supplies necessary to respond to any such eventuality. It is also mitigated by exclusion of patients with known allergy to the product. Risks associated with multiple iterations of bag/mask ventilation are mitigated by the presence of attending anesthesiologists, who are experts in all aspects of airway management. The remaining listed risks are mitigated by adherence to procedures as described in this document as well as routine HRRC policies/procedures.

18.3. The investigators have not identified any aspects of this study that may carry unforeseeable additional substantial risks.

19. Potential Benefits to Subjects

19.1. Investigators have not identified any direct benefits for participants.

20. Recruitment Methods

20.1. Potential subjects will be recruited from among UNM Hospital surgical patients, who are regular patients of the investigators, in the pre-operative holding areas

during the routine pre-surgical consultation between the anesthesia provider and patient. An investigator, who is also one of the potential participant's treating physicians, will first ask whether the patient is interested in participating in research about airway management in bearded patients. If the patient expresses interest, the study will be explained in more detail and the consent process will commence.

20.2. Clinician investigators will review patients' charts prior to surgery in the context of their own scheduled treatment of the patient. Patient characteristics in the inclusion/exclusion criteria will be screened for to identify patients that meet such criteria with perioral facial hair greater than 5mm in length.

20.3. Recruitment will be verbal only; no advertisements will be used.

21. Provisions to Protect the Privacy Interests of Subjects

Recruitment will occur in the pre-operative holding areas, which are already sufficiently private for confidential doctor/patient conversations. Recruitment will be handled by clinicians already authorized and expected to contact relevant patients. Recruitment and consent will not require the disclosure of information beyond routine medical information. The patient experience will not be greatly modified by participation in this study; the only change is the additional use of Tegaderm™ during mask ventilation for a duration of 60 seconds prior to intubation and the use of the pneumotachograph device in the preexisting anesthesia circuit to measure airflow. Participants will not be observed by atypical personnel.

22. Economic Burden to Subjects

22.1. Patients (or their 3rd-party payers) will be responsible for routine costs of surgery, but not placement of the Tegaderm™. It is not anticipated that this additional intervention will change the patient cost as a result of study participation.

Research Procedures	**Number of Samples/Procedures**	**Responsible Party**	
		Study	**3rd Party Payer or Participant**
Tegaderm™ placement	All	☒	☐
_____	_____	☐	☐
_____	_____	☐	☐
Standard of Care Procedures	**Number of Samples/Procedures**	**Responsible Party**	
		Study	**3rd Party Payer or Participant**
Surgery	All	☐	☒
Anesthesia	All	☐	☒
Hospitalization (as appropriate)	All	☐	☒
Medications and supplies	All	☐	☒
_____	_____	☐	☐

22.2. Patients (or third-party payers) will be responsible for any costs related to adverse outcomes; this is discussed in the consent form.

23. Compensation

23.1. Participants will not be compensated.

24. Compensation for Research-Related Injury

24.1. Subjects will be responsible for any costs of research-related-injury. This is communicated in the consent documentation.

25. Consent Process

25.1. Consent will be obtained prior to commencement of research activities.

- An investigator will obtain consent. All investigators have completed appropriate HIPAA, CITI, and related training as required by UNM HSC and by HRRC.
- The consent process will take place in the pre-operative holding areas immediately after recruitment. These areas are sufficiently private for confidential doctor-patient conversations.
- The possibility of coercion or undue influence is reduced in several ways. All participants are drawn from a population that require mask ventilation. There is no compensation for participation. All prospective participants will be assured that there is no consequence for declining participation; participation is strictly voluntary.
- Participation in this entails the use of and previously described intervention for bearded patients and one that is routinely used when complicated airways are encountered. The consent decision is thus comparably complex to the decisions surrounding anesthesia management that are already routinely handled entirely within the preoperative anesthesia consultation. The appropriateness of day-of-surgery consent for anesthesia studies has also been the topic of scientific investigation, and the results clearly indicated that longer intervals in which to consider participation do not automatically benefit participants. This recent study (Murphy et al., "Consent for Anesthesia Clinical Trials on the Day of Surgery," Anesthesiology 2016; 124:1246-55) showed that patients approached for consent to participate in anesthesia-related research on the day of surgery tend to be satisfied with the consent process, feel that the protocol was well explained and comprehended, and that the setting was appropriate. Conversely, these patients **strongly disagreed** that they were anxious at the time of consent, felt obligated to participate, or regretted participating. Importantly, the use of a preadmission telephone call to describe the research protocol and provide extended time for patients to consider their participation did not change these results.
- Investigators do not anticipate that ongoing consent will be at issue during this study, because patients' active participation will only occur prior to anesthesia.

- Consenting investigators will ask prospective participants to describe the study briefly in their own words in order to ensure understanding.
- Subjects will be given a copy of the signed consent.

Subjects not fluent in English

- The investigators will primarily enroll patients who speak English but will include occasional Spanish speakers as well. A majority of UNM Hospital surgical patients do speak English, so relatively few patients with insufficient English fluency to understand the consent materials would be encountered during the enrollment period. The investigators anticipate that most non-English speakers would speak Spanish, so we will use the hospital translation service and the Spanish Short Form Consent document. Patients who do not speak English or Spanish will not be enrolled.

Cognitively Impaired Adults/Adults Unable to Consent/Use of a Legally Authorized Representative

- Patients in this category will not be enrolled.

Subjects who are not yet adults (infants, children, teenagers)

- Patients in this category will not be enrolled.

Waiver or Alteration of Consent Process (consent will not be obtained, required element of consent will not be included, or one or more required elements of consent will be altered)

- As noted elsewhere in this protocol, the investigators will use their already-authorized review of patient records (as part of routine clinical care; these are their patients) to screen for eligibility, and therefore request HIPAA waiver for screening purposes. The investigators are not seeking other waiver or alteration of the consent process.

26.Documentation of Consent

26.1. A proposed consent form is included with this application.

27.Study Test Results/Incidental Findings

27.1. **Individual Results:** This study does not involve laboratory tests or other findings outside routine medical care. Relevant routine information is already shared with patients as appropriate, and this study does not change the delivery of information to patients.

27.2. ***Incidental Findings:*** The investigators do not anticipate any incidental findings to be generated by this study.

28.Sharing Study Progress or Results with Subjects

28.1. Investigators do not plan to share in-progress study results with patients.

28.2. Investigators do not plan to share final study results with patients.

29.Inclusion of Vulnerable Populations

29.1. This research does not target any of the populations typically identified as vulnerable.

30. Community-Based Participatory Research

30.1. NA.

31. Research Involving American Indian/Native Populations

31.1. NA

32. Transnational Research

32.1. NA

33. Drugs or Devices

33.1. This study includes the use of Tegaderm™ bandage. In consultation with UNM HSC HRPO staff, the investigators believe that this study is IDE exempt.

34. Principal Investigator's Assurance

By submitting this study in the Click IRB system, the principal investigator of this study confirms that:

☒ The information supplied in this form and attachments are complete and correct.

☒ The PI has read the Investigator's Manual and will conduct this research in accordance with these requirements.

☒ Data will be collected, maintained and archived or destroyed per HSC Data Security Best Practices, including:

1. **Best Practice for data collection** is for it to be directly entered onto a data collection form that is in a secured access folder on an HS drive behind a firewall, or in a secure UNM Data Security approved system such as RedCap.
2. **Data collection of de-identified data**, if done in a clinical setting or other setting that does not allow direct entry into a secured system, may be done temporarily using a personal or university owned electronic storage device or hard copy document. **The important security safeguard is that no identifiers be include if the data is entered or stored using an untrusted device or storage.**
3. **Permanent (during data analysis, after study closure**) storage must reside on HSC central IT managed storage. Processing of data (aggregation, etc.) are to be carried out in such a way as to avoid creating/retaining files on untrusted storage devices/computers. Trusted devices are HSC managed and provide one or more of following safeguards: access logs, encryption keys, backups, business continuity and disaster recovery capabilities.
4. **Alternate storage media** must be approve by HSC IT Security as meeting or exceeding HSC central IT provided security safeguards.

Checklist Section

This section contains checklists to provide information on a variety of topics that require special determinations by the IRB. Please complete all checklists relevant to your research.

I. Waivers or Alterations of Consent, Assent, and HIPAA Authorization

A. Partial Waiver of Consent for Screening/Recruitment
NA; the primary screening criterion for inclusion is the presence of a beard, which does not constitute PHI. Other inclusion/exclusion criteria are already part of the routine review of records conducted prior to surgery.

Partial Waiver of HIPAA Authorization for Screening/Recruitment

The investigators already review relevant patients' records for treatment purposes; these are their patients and this review is part of routine care. The investigators are requesting partial waiver of HIPAA authorization for screening purposes. The reviewed criteria are quite straightforward and do not require recording at the screening phase.

A. Will you be recording any PHI when conducting the records review to identify potential subjects and/or determine eligibility?

☐ Yes. Describe:

☒ No

B. If you answered "Yes" to question 6 above, please describe when you will destroy identifiers (must be the earliest opportunity consistent with the conduct of the research) or provide justification for why they must be retained:

C. The PHI accessed or recorded for identification/screening purposes will not be reused or disclosed to (shared with) any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of the PHI would be permitted under the Privacy Rule.

☒ True

☐ False

B. Waiver of Documentation of Consent
NA; this waiver is not being sought.

C. Alteration of Consent
NA; no alteration is being sought.

D. Full Waiver of Consent/Parental Permission

Tegaderm™ Placement for Bag Mask Ventilation in the Bearded Patient

NA

E. Full Waiver of Consent/Parental Permission (Public Benefit or Service Programs)
NA

F. Full Waiver of HIPAA Authorization
NA

G. Other Waiver Types
NA

II. Vulnerable Populations

NA; vulnerable populations are not included.

III. Medical Devices

Complete this checklist if the research evaluates the safety or effectiveness of a medical device. If more than one medical device is being evaluated, provide the requested information for each.

A. Device Name: Tegaderm™ dressing

B. Manufacturer: 3M

C. Does the research involve a Significant Risk Device under an IDE?

☐ Yes. Include documentation of the FDA approval of the IDE with your submission. *Acceptable methods of documentation include: (1) FDA letter noting IDE number and approval status; (2) Industry sponsor letter noting IDE number and FDA approval status; or (3) FDA-approved industry sponsor protocol with IDE number noted*

☐ No

D. Is the research IDE-exempt?

☒ Yes. Include a FDA letter with your submission noting the determination that the research is IDE-exempt or a letter from the sponsor (or sponsor-investigator) justifying why they believe the research is IDE-exempt*.

☐ No

E. Does the research involve a Non-Significant Risk (NSR) Device?

☐ Yes. Include a FDA letter with your submission noting the determination that the research is NSR or a letter from the sponsor (or sponsor-investigator) justifying why they believe the research is NSR**.

Tegaderm™ Placement for Bag Mask Ventilation in the Bearded Patient

☒ No

* This FDA guidance includes a description for when a device study is exempt from the IDE requirements: http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM127067.pdf

**This FDA guidance includes information on how to differentiate between Significant Risk and Non-Significant Risk device studies: http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM126418.pdf

IV. Export Control:

NA