Supplementary file to:

Bougie or Stylet In Patients Undergoing Intubation Emergently (BOUGIE): protocol and statistical analysis plan

Driver B, *et al. BMJ Open* 2021; 11:e047790. doi: 10.1136/bmjopen-2020-047790

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1. SPIRIT 2013 Checklist

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Addressed on page number
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	5
	2b	All items from the World Health Organization Trial Registration Data Set	1-5
Protocol version	3	Date and version identifier	N/A
Funding	4	Sources and types of financial, material, and other support	2-3
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	1,2
	5b	Name and contact information for the trial sponsor	2
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	2-3

	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	1,2, 16
Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	7-8
	6b	Explanation for choice of comparators	7-8
Objectives	7	Specific objectives or hypotheses	8
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	8
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	8
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centers and individuals who will perform the interventions (eg, surgeons, psychotherapists)	8-9
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	10-11
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	11-12

	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	10-11
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	11-12
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	13-15
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	Table 1
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	15
Recruitment	15	Strategies for achieving adequate participant enrollment to reach target sample size	15
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enroll participants or assign interventions	9-10
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	9-10

Implementation	16c	Who will generate the allocation sequence, who will enroll participants, and who will assign participants to interventions	9-10
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	10
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	N/A
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	12-14
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	12-14
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	12-14
Statistical methods	20a	Statistical methods for analyzing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	16-19
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	16-19
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomized analysis), and any statistical methods to handle missing data (eg, multiple imputation)	16-20

Methods: Monitoring

Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	16, Supplement section 6
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	16
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	Supplement section 6
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	Supplement section 6

Ethics and dissemination

Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	8
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	Supplement section 8
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorized surrogates, and how (see Item 32)	20-21
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	N/A
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	Supplement section 7

Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	3
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	Supplement section 7
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	N/A
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	4
	31b	Authorship eligibility guidelines and any intended use of professional writers	N/A
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	Supplement section 7
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorized surrogates	N/A
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	N/A

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.

2. Site Characteristics

Table S1

	VUMC ICUs	VUMC ED	LSU UMCNO MICU	Ochsner MICU	UAB MICU	UAB ED
Patient Notification Strategy	Information Sheet	Information Sheet	Information Sheet	Information Sheet	Notification Sheet	Notification Sheet
IRB Process	Central*	Central*	Central	Central	Central	Central

	WFU MC ED	U of CO ED	DHMC ED	UW-Harborview ICU	Lincoln Medical Center
Patient Notification Strategy	Information Sheet	Notification Sheet	Notification Sheet	Information Sheet	Notification sheet
IRB Oversight	Central	Central	Central	Central	Local

VUMC is Vanderbilt University Medical Center in Nashville, TN; LSU is Louisiana State University Medical Center New Orleans, in New Orleans, LA; Oschner is Ochsner Medical Center, in New Orleans, LA; UAB is University of Alabama at Birmingham in Birmingham, AL; WFU is Wake Forest University Medical Center in Winston-Salem, NC; U of CO is University of Colorado in Aurora, CO; DHMC is Denver Health Medical Center in Denver, CO; UW-Harborview is University of Washington in Seattle, WA; Lincoln Medical Center is Lincoln Medical Center in Bronx, NY.

ED, emergency department; ICU, intensive care unit; MICU, medical ICU; SICU, surgical ICU; IRB is institutional review board. “Notification sheet” is a patient and family notification packet provided to each patient and family following enrollment informing the patient of his or her enrollment and describing the study. “Information Sheet” is a patient and family information sheet containing general information about the study and contact information for the research team displayed in at least three publicly-visible locations within the study unit. *The Vanderbilt IRB served as central IRB for sites utilizing a central IRB process.

3. List of BOUGIE Investigators

Vanderbilt University Medical Center— Matthew W. Semler, MD, MSc***; Wesley H. Self, MD, MPH***; Christopher G Hughes, MD, MS***; Janna S. Landsperger, MSN***; Li Wang, MS***; Christopher J. Lindsell PhD***; Todd W. Rice, MD, MSc***; Jonathan D. Casey, MD, MSc***; Christopher S. Gray, RN**; Kevin High, RN, MPH**; Andrea Fletcher, RN**; Sally Dye, RN**; Bradley Lloyd, RRT-ACCS*; Bret D. Alvis, MD*.

University of Colorado School of Medicine— Adit A Ginde, MD, MPH***; Michelle P Howell, RN, BSN***; Robert Mitchell, RRT**; Justin Oeth, RN, MSN**; Anthony Defebio*; Jennifer Friedel*; Feysel Mohamed*; Karina Nava*; Angela Otoo*; Christian Perez*; Cori Withers*.

University of Alabama at Birmingham Medical Center— Sheetal Gandotra, MD***; David B Page, MD***; Micah R Whitson, MD***; Derek W. Russell, MD***; Swati Gulati, MBBS, MS***; Sarah W. Robison, MD**; Michael C. Kurz, MD, MS**; Anna Altz-Stamm RN, BSN, CCRN*; Cristina Bardita, MD, PhD*; Mary Clay Boone RN, BSN*; Joe W. Chiles III, MD*; Kristina Collins RN, BSN*; Abby Drescher RN, BSN*; Kevin G. Dsouza, MD*; Janna Dunn, RN, ADN*; Stacy Ejem, MD*; Josh Gautney, MD*; Nicole Harris, RN, ADN*; Savannah Herder, RN, BSN*; Tamer Hudali, MD, MPH*; R. Chad Wade, MD*; Rutwij Joshi, MBBS*; Daniel Kelmenson, MD*; Anne Merrill Mason RN, BSN*; Scott R. Merriman, MD*; Takudzwa Mkorombindo, MD*; Megan Moore, RN, MSN*; Jada Nowak, RN, BSN*; Kate O'Connor, DO*; Sheylan D. Patel, MD*; G. Bruno Pereira, MD, PhD*; Lisa Sarratt RN, BSN*; Tabitha Stewart RN, BSN*; William S. Stigler, MD*; Kadambari Vijaykumar, MBBS*; Gina White RN, BSN*; Stephanie C. Demasi, MD*; Laura E. Goyack, MD*.

Denver Health Medical Center— Stacy A Trent, MD, MPH***; Carol L. Lyle, MPH, PA-C**; Alicia K. Cupelo, MSW**.

Wake Forest School of Medicine— Lane M Smith, MD, PhD***; John P Gaillard, MD***; Kevin W. Gibbs, MD***; Erika L.W. Rice, DO**; Nathaniel D. Westphal, MD**; Kristy K. Ford, MD*; Trevor S. Mattox, MD*.

Ochsner Health System New Orleans— Derek J Vonderhaar, MD***.

University of Washington Harborview Medical Center— Aaron M. Joffe, DO***; Itay Bentov, MD, PhD***; Steven H Mitchell, MD***; Andrew J Latimer, MD***; Christopher Barnes**; Andrew M. Walters**; Tak Watase, MD MBA*.

Lincoln Medical Center— Jason R West, MD***.

University of Iowa Hospitals and Clinics— Kevin Doerschug, MD***; Vikas Koppurapu, MD**.

Duke University School of Medicine— Vijay Krishnamoorthy, MD, PhD*; Raquel R Bartz, MD*; William C Fox, MD*; John Whittle, MBBS, MD*.

Louisiana State University School of Medicine—David R Janz, MD, MSc***.

Hennepin County Medical Center— Brian E Driver, MD***; Matthew E Prekker, MD MPH***; Jamie Stang, BS**; Paige DeVries, BS**; Alexandra Schick, MD**.

***Denotes an author listed on the byline.
**Denotes an author not listed on the byline due to space considerations.
*Denotes a collaborator

4. Definition of ICU-Free Days (ICU-FDs)

ICU-FDs are defined as the number of days, between enrollment and 28 days after enrollment, in which the patient is alive and not admitted to an intensive care unit service after the patient's final discharge from the intensive care unit. Patients who are never discharged from the intensive care unit receive a value of 0. Patients who die before day 28 receive a value of 0. For patients who return to an ICU and are subsequently discharged prior to day 28, ICU-free days are counted from the date of final ICU discharge. All data are censored hospital discharge or 28 days, whichever comes first.

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5. Definition of Ventilator Free Days (VFDs)

VFDs are defined as the number of days, between enrollment and 28 days after enrollment, during which the patient is alive and with unassisted breathing and remains free of assisted breathing. If a patient returns to assisted breathing and subsequently achieves unassisted breathing prior to day 28, VFD will be counted from the end of the last period of assisted breathing to day 28. If the patient is receiving assisted ventilation at day 28 or dies prior to day 28, VFDs are 0. If a patient is discharged while receiving assisted ventilation, VFDs are 0. All data is censored hospital discharge or 28 days, whichever comes first.

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6. Data and Safety Monitoring Board Charter

DATA AND SAFETY MONITORING BOARD CHARTER

Charter, Data and Safety Monitoring Board for

Bougie or Stylet In Patients Undergoing Intubation Emergently: BOUGIE

BOUGIE STEERING COMMITTEE

Protocol Co-Chairs	Brian Driver MD
	Assistant Professor of Emergency Medicine
	Hennepin County Medical Center and University of Minnesota Matthew Prekker MD, MPH
	Assistant Professor of Emergency Medicine and Pulmonary and Critical Care Medicine
	Hennepin County Medical Center and University of Minnesota
Coordinating Center	Vanderbilt University Medical Center
	Director: Jonathan D. Casey MD
	ED Site Director: Wesley H. Self, MD, MPH
	ICU Site Director: Todd W. Rice, MD, MSc
Network	Pragmatic Critical Care Research Group (PCCRG)
	Steering Committee Chair: Matthew W. Semler MD, MSc

Charter, Data and Safety Monitoring Board for

"Bougie or Stylet In Patients Undergoing Intubation Emergently: BOUGIE"

November 2018

1. Introduction

This Charter is for the Data and Safety Monitoring Board (DSMB) for "Bougie or Stylet In Patients Undergoing Intubation Emergently: The BOUGIE Trial"

The Charter is intended to be a living document. The DSMB may wish to review it at regular intervals to determine whether any changes in procedure are needed.

2. Responsibilities of the DSMB

The DSMB is responsible for safeguarding the interests of study participants, assessing the safety and efficacy of study procedures, and for monitoring the overall conduct of the study.

The DSMB is an independent group advisory to the BOUGIE Trial Steering committee and is assembled to provide recommendations about starting, continuing, and stopping the trial. In addition, the DSMB is asked to make recommendations, as appropriate, to the investigators about:

- Benefit/risk ratio of procedures and participant burden
- Selection, recruitment, and retention of participants
- Adherence to protocol requirements
- Completeness, quality, and analysis of measurements
- Amendments to the study protocol
- Performance of individual centers
- Participant safety
- Notification of and referral for adverse events

3. Organization and Interactions

Communication with DSMB members will be primarily through Dr. Casey. It is expected that neither BOUGIE Trial Steering Committee members nor study investigators will communicate with DSMB members about the study directly, except when making presentations or responding to questions at DSMB meetings or during conference calls.

4. DSMB Members

DSMB members and their expertise are listed in Appendix A. The DSMB consists of four physicians (Dr. Hooper, the DSMB chair, Dr. Lammi, Dr. Hernandez, and Dr. Storrow) who are experienced in the care of

critically ill patients, the conduct of clinical trials, and the process of data and safety monitoring. All three members of the DSMB have formal training to conduct statistical analyses necessary for the planned interim analysis. Dr. Casey or his designee will serve as the Executive Secretary (ES) and be responsible for keeping the minutes during open sessions. The Chair of the DSMB will be responsible for recording the minutes of the closed sessions and for the timely transmission of the final DSMB recommendations to the BOUGIE Trial Steering Committee, who will be responsible for the timely notification of investigators of all DSMB recommendations.

If one of the DSMB members resigns for any reason, a replacement member will be chosen by the chair of the DSMB, in collaboration with the BOUGIE Trial steering committee. If the DSMB chair resigns from the DSMB, one of the remaining DSMB members will be chosen to serve as the chair of the DSMB and a replacement member will be chosen by the BOUGIE Trial Steering Committee.

5. Scheduling, Timing, Content, and Organization of Meetings

DSMB meetings will be held by teleconference. The purpose of the first meeting is to review and discuss this Charter and the study protocol, including the Data Safety Monitoring Plan. Dr. Casey or his designee can conduct this meeting with individual DSMB members or as a group. Enrollment in the study cannot begin until the BOUGIE Trial Steering Committee has accepted the DSMB's recommendation for approval and IRB approval has been obtained. All DSMB members must sign and return the charter to Dr. Casey or his designee to indicate their approval.

Conference calls are to be held twice per year, with additional conference calls scheduled as needed. Depending on the timing of the interim analysis, and at the discretion of the DSMB, the interim analysis may take the place of one of the biannual conference calls. Conference calls will be scheduled by Dr. Casey or his designee in collaboration with the DSMB members.

The DSMB will perform an interim analysis to review 30-day data after the enrollment of 553 subjects; enrollment will continue during the DSMB review. The primary focus of this review will be efficacy and safety. The DSMB will be supplied with raw data for the outcomes required for these analyses (as described below). Dr. Casey or his designee will also provide the DSMB committee with additional summary statistics on baseline characteristics, by group. The DSMB may request any additional data, as needed. The DSMB will also be able to request unblinding for any reason. All DSMB members must be present during this session and all must vote at the end of the session on the continuation of the trial. All serious adverse events thought to be related to study procedures will be reported to the DSMB on an ongoing basis; the study will be stopped for a safety evaluation by the DSMB if they have any concerns based on either the interim data analysis or review of serious adverse events.

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The agenda for DSMB meetings and calls will be drafted by Dr. Casey or his designee. Dr. Casey or his designee will finalize the agenda after consultation with the DSMB Chair. The agenda and meeting materials will be distributed prior to each call.

Before each teleconference Dr. Casey or his designee will ask all DSMB members to state whether they have developed any new conflicts of interest since the last call. If a new conflict is reported, the Chair will determine if the conflict limits the ability of the DSMB member to participate in the discussion. If the Chair reports a new conflict, the BOUGIE Trial Steering Committee will determine if the conflict limits the ability of the Chair to participate in the discussion.

It is expected that all DSMB members will attend every call and respond to electronic mail communications promptly. A quorum of this DSMB will be all three members.

6. Discussion of Confidential Material

DSMB meetings and calls will be organized into open, closed, and executive sessions.

- During the **open sessions**, Dr. Casey or his designee will present information to the DSMB on behalf of the study investigators with time for discussion.

- During the **closed sessions**, the DSMB will discuss confidential and/or unblinded data from the study. Steps will be taken to ensure that only the appropriate participants are on the call, and to invite others to re-join the call only at the conclusion of the closed session.

- The DSMB may elect to hold an **executive session** in which only the DSMB are present in order to discuss study issues independently. Voting on recommendations will follow Roberts' Rules of Order (**Robert's Rules of Order Newly Revised (10th Edition) RONR** by Henry M. Robert III, William J. Evans (Editor), Daniel H. Honemann (Editor), Thomas J. Balch (Editor), Sarah Corbin Robert, Henry M. Robert III, General Henry M. Robert). If the executive session occurs on a conference call, steps will be taken to ensure that only the appropriate participants are on the call, and to invite others to re-join the call only at the conclusion of the executive session.

At the conclusion of the closed and executive sessions, the participants will be re-convened so that the DSMB Chair can provide a summary of the DSMB's recommendations. This provides an opportunity for study investigators to ask questions to clarify the recommendations. The meeting is then adjourned.

7. Reports of DSMB Deliberations

- Initial summary: Dr. Casey is responsible for ensuring the accuracy and transmission of a brief summary of the DSMB's discussion and recommendations. The BOUGIE Trial Steering committee will review this summary and approve or disapprove the recommendation(s), or request additional information. The recommendations will then be sent to the clinical investigators.

- Action plan: If the DSMB's recommendations require significant changes or follow-up, the BOUGIE Trial Steering Committee will prepare an action plan outlining the steps required to implement the recommendations.

- Formal minutes: As the Executive Secretary, Dr. Casey is responsible for the accuracy and transmission of the formal DSMB minutes within 30 days of the meeting or call. These minutes are prepared accordingly to summarize the key points of the discussion and debate, requests for additional information, response of the investigators to previous recommendations, and the recommendations from the current meeting. The DSMB Chair may sign the minutes or indicate approval electronically via email.

8. Reports to the DSMB

For each meeting, Dr. Casey will prepare summary reports and tables to facilitate the oversight role of the DSMB. The DSMB will discuss at the first meeting what data they wish to review and how it should be presented. Data requests can be modified at subsequent meetings.

9. Statistical Monitoring Guidelines

At the first meeting, review of the protocol will include review of the clinical endpoints and safety monitoring plans. The DSMB should discuss the adequacy of that plan. The DSMB should discuss the statistical monitoring procedures they propose to follow to guide their recommendations about termination or continuation of the trial.

10. Stopping Rules

The DSMB will conduct a single interim analysis for efficacy and safety at the anticipated halfway point of the trial, at least 30 days after enrollment of 553 patients. Enrollment will continue during this period. One week prior to the meeting for the interim analysis, Dr. Casey or his designee will provide the DSMB with the following blinded data in raw format:

1. Study group assignment of each patient (A vs B)

2. The primary outcome (successful intubation on the first attempt)
3. Esophageal intubation (safety outcome)
4. Airway trauma

For this interim analysis, the DSMB will be asked to perform an efficacy analysis and a safety analysis as described below. At the completion of these analyses, the DSMB will notify the BOUGIE Trial Steering Committee of their recommendation for the trial to be stopped or continued to completion. If the trial is not stopped, the DSMB will not make the steering committee members or any of the investigators aware of the results of any of their analyses. At the interim analysis or at any other time where the DSMB is deciding if the trial should be stopped or continued, all members of the DSMB must agree that the trial should be stopped or continued.

11. Efficacy and Safety Stopping Rule

The **stopping boundary for efficacy** will be met if the P-value using a chi-square test for the difference between groups in the primary outcome of successful intubation on the first attempt is 0.001 or less. Using this conservative Haybittle–Peto boundary ($P \leq 0.001$) will allow the final analysis to be performed using an unchanged level of significance.

The **stopping boundary for safety** will be met if the P-value using a chi-square test for the difference between groups in the either of the safety outcomes, esophageal intubation, or airway trauma, is 0.025 or less.

If requested by the DSMB, the DSMB will be provided with blinded data on all outcomes collected by the trial to use in their review of trial safety. Additionally, the DSMB will reserve the right to stop the trial at any point, request additional data or interim analyses, unblind the study assignments, or request modifications of the study protocol as required to protect patient safety.

Appendix A: DSMB members and titles

Michael Hooper, MD, MSc (DSMB Chair)

Associate Dean for Clinical Education, Associate Professor

Allergy, Pulmonary and Critical Care Medicine

Eastern Virginia Medical School

Expertise: Critical care, clinical trials, data and safety monitoring

Matthew Lammi, MD, MSc

Associate Professor of Medicine

Section of Pulmonary/Critical Care and Allergy/Immunology

LSU School of Medicine New Orleans

Expertise: Critical care, clinical trials, biostatistics

Alan B. Storrow, MD

Associate Professor

Department of Emergency Medicine

Associate Director of Research

Center for Emergency Care Research and Innovation (CERI)

Expertise: Emergency medicine, clinical research, quality improvement, patient safety

Antonio Hernandez, MD

Associate Professor

Department of Anesthesiology

Vanderbilt University Medical Center

Expertise: Critical care, intubation, clinical research

7. Patient Privacy and Data Storage

At no time during the course of this study, its analysis, or its publication, will patient identities be revealed in any manner. The minimum necessary data containing patient or provider identities or other private healthcare information (PHI), is collected. All subjects are assigned a unique study ID number for tracking. Data collected from the medical record is entered into the secure online database REDCap. The PHI required to accurately collect clinical and outcomes data is available only to investigators at the site at which the subject is enrolled, and this data is shared only in completely de-identified form with the coordinating center via the secure online database REDCap. Hard copies of the data collection sheet completed at the time of the airway management event are stored in a locked room until after the completion of enrollment and data cleaning. Once data are verified and the database is locked, all hard copies of data collection forms will be destroyed. The de-identified dataset housed in REDCap will be accessed by the coordinating center for reporting the results of this trial. All data will be maintained in the secure online database REDCap until the time of study publication. At the time of publication, all PHI at local centers will be expunged and only the de-identified version of the database will be retained. Potential future use of de-identified data generated in the course of this study by the coordinating center and other participating sites is allowed and will be governed by mutual data sharing use agreements.

8. Plan for communication of protocol changes

Any changes to the trial protocol (e.g., changes to eligibility criteria, outcomes, analyses) will be implemented via a new version of the full trial protocol, tracked with the date of the update and the version number of the trial protocol. A list summarizing the changes made with each protocol revision will be included at the end of each protocol. The updated protocol will be sent to the relevant IRBs for tracking and approval prior to implementation of the protocol change. At the time of publication, the original trial protocol, and the final trial protocol, including the summary of changes made with each protocol change, will be included in the supplementary material for publication.

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