Trials

STUDY PROTOCOL

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Effect of ultrasound-guided internal branch of superior laryngeal nerve block on postoperative sore throat induced by a NIM-EMG-ETT: study protocol for a double-blinded randomized controlled trial

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Abstract

Background Postoperative sore throat (POST) is a common complaint after general anaesthesia. The prevalence of POST caused by a neural integrity monitor electromyography endotracheal tube (NIM-EMG-ETT) is high. This study aimed to determine whether ultrasound-guided internal branch of superior laryngeal nerve block (iSLNB) could alleviate POST associated with a NIM-EMG-ETT.

Methods This randomized controlled trial plans to enroll 182 patients scheduled to undergo general anaesthesia with a NIM-EMG-ETT. Patients will be randomly allocated into the iSLNB group or the control group according to randomized numbers generated by Excel. After induction, patients in the iSLNB group will undergo ultrasound-guided iSLNB with ropivacaine, and patients in the control group will undergo the same procedure with normal saline. The prevalence, severity, visual analogue scale score of POST, and postoperative acoustic analysis will be recorded.

Discussion To the best of our knowledge, this is the first study to evaluate the effect of ultrasound-guided iSLNB with ropivacaine on the mitigation of POST induced by NIM-EMG-ETT. Our study will provide clinical answers to alleviate POST induced by NIM-EMG-ETT. The results of this study may provide a safe method to prevent POST caused by NIM-EMG-ETT.

Trial registration Chinese Clinical Trial Registry, ChiCTR2300076393. Registered on October 24, 2023, http://www.chictr.org.cn/index.aspx.

Keywords Pharyngitis, Postoperative complication, Endotracheal intubation, Intraoperative neurophysiological monitoring, Ultrasound-guided internal branch of superior laryngeal nerve block

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Administrative information

Note: the numbers in curly brackets in this protocol refer to SPIRIT checklist item numbers. The order of the items has been modified to group similar items (see http://www.equator-network.org/reporting-guidelines/spirit-2013-statement-defining-standard-protocol-items-for-clinical-trials/).

Title {1}	Effect of ultrasound-guided superior laryngeal nerve block on postoperative sore throat induced by a NIM-EMG-ETT: study protocol for a double-blinded randomized controlled trial.
Trial registration {2a and 2b}.	Chinese Clinical Trail Registry, ChiCTR2300076393. Registered on October 24, 2023. (http://www.chictr.org.cn/index.aspx)
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Author details {5a}	All of the authors are from Shanghai Sixth People's Hospital Affiliated with Shanghai Jiao Tong University School of Medicine
Name and contact information for the trial sponsor {5b}	Name: Shanghai Sixth People's Hospital Affiliated with Shanghai Jiao Tong University School of Medicine Contact information: No. 600, Yishan Road, Xuhui District, Shanghai, China.
Role of sponsor {5c}	The sponsor of this study will give financial support to this study and supervise the process of the trial.

Introduction

Background and rationale {6a}

Postoperative sore throat (POST) following endotracheal intubation is an important concern in surgical patients [1]. Compared with a standard endotracheal tube (ETT), a neural integrity monitor electromyography ETT (NIM-EMG-ETT) results in more severe POST. The prevalence of POST induced by NIM-EMG-ETT was 89.4% in our previous study [2]. Although surgical pain is well controlled after the use of narcotics, POST is difficult to treat and may worsen when swallowing [3]. Many studies have attempted to attenuate POST, such as injecting dexamethasone or lidocaine intravenously [4, 5], choosing ETTs with smaller sizes, and using lubricants before intubation [6]. However, some researchers consider that the effects of all of these methods are not satisfactory [7]. A cohort study revealed that superior laryngeal nerve block (SLNB) effectively alleviated POST [8]. Ramkumar and colleagues reported that SLNB reduced the incidence of POST [9]. The internal branch of the laryngeal nerve block (iSLNB) has been shown to alleviate POST caused by a general ETT [10] or a double-lumen tube [11].

We hypothesize that iSLNB can reduce the prevalence of POST associated with NIM-EMG-ETT. In this study, we aim to explore the effect of iSLNB on POST induced by NIM-EMG-ETT.

Objectives {7}

The aim of our study is to determine whether ultrasound-guided iSLNB will reduce the prevalence of POST in patients undergoing elective thyroidectomy with a NIM-EMG-ETT.

Trial design {8}

This is a single-centre, prospective, 1:1 randomized controlled, double-blinded study. The framework for the trial is superiority. The schedule of the enrolment and the assessments is presented in the Standard Protocol Items: Recommendations for Interventional Trials figure (Figs. 1 and 2).

Methods: participants, interventions and outcomes

Study setting {9}

This trial will be conducted at Shanghai Sixth People's Hospital Affiliated with Shanghai Jiao Tong University School of Medicine, Shanghai, China, where approximately 200 elective thyroidectomies with NIM-EMG-ETTs are performed every month.

Eligibility criteria {10}

Prior to enrolment, patients must comply with all of the following criteria: (1) undergoing elective thyroidectomy with a NIM-EMG-ETT; (2) aged 18–75 years; (3) American Society of Anesthesiologists' (ASA) physical status classes I–II; and (4) provided informed consent.

Patients will be excluded if they meet one of the following criteria: (1) lack of consent; (2) pre-existing allergies to local anaesthesia agents and other contraindications to iSLNB, intraoperative neuromonitoring (IONM) or the medications used in the study; (3) neurological or psychiatric disease; (4) anticipated difficult intubation and preoperative identification of respiratory diseases; (5) pregnant or lactating women; (6) duration of tracheal intubation of more than three hours; or (7) receiving analgesic therapy within 2 weeks before surgery.

	Study period						
	Enrollment		Follow-up (after extubation)				
TIMEPOINT	-1 day	Surgery day	1 h	3 h	8 h	24 h	48 h
ENROLLMENT							
Eligibility screen	×						
Informed consent	×						
Allocation	×						
INTERVENTIONS							
Ultrasound-guided iSLNB group		×					
Control group		×					
ASSESSMENTS							
Clinical characteristics	×	×					
Vital sign		×	×	×	×	×	×
Intraoperative fentanyl dose		×					
Prevalence of POST			×	×	×	×	×
Severity of POST			×	×	×	×	×
VAS of POST			×	×	×	×	×
Voice recorded		×	×	×	×	×	×
Extubation time		×					
Complications and adverse events			×	×	×	×	×

Fig. 1 Standard protocol items: recommendations for interventional trials schedule of enrollment, intervention and assessments. h hour, iSLNB internal branch of superior laryngeal nerve block, POST postoperative sore throat, VAS visual assessment score

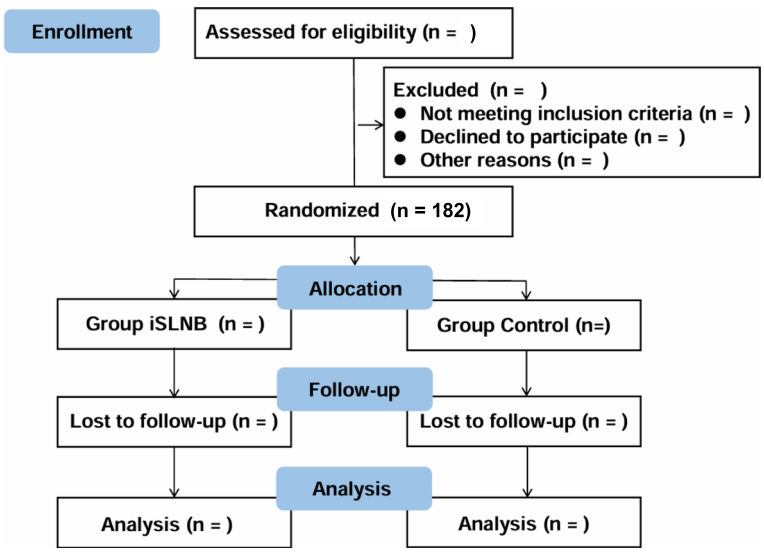

Fig. 2 A consolidated standards of reporting trials flow diagram

Anaesthesiologists with more than five years of clinical experience will perform the intervention.

Who will take informed consent? {26a}

Patients who are planning to undergo thyroidectomies with IONM will be screened for eligibility to participate in this study on the basis of the abovementioned criteria. After the patient has been assessed as eligible by one researcher, they will receive initial study information and discuss questions with the researcher. After all of the questions have been answered, the patient will be asked to sign the informed consent form.

Additional consent provisions for collection and use of participant data and biological specimens {26b}

Not applicable. There are no additional consent provisions for the collection and use of participant data and biological specimens in ancillary studies.

Interventions

Anaesthesia induction

None of the subjects will receive premedication before anaesthesia, and all patients will refrain from solid foods for 6 h and clear fluids for 2 h preoperatively. Patient voice data (recordings) will be collected as soon as the participants are transferred to the operating room. After intravenous access is established, standard ASA monitors will be attached. All of the monitor values will be recorded every 5 min. Then, anaesthesia will be induced with dexamethasone 5 mg, propofol 2 mg/kg, sufentanil 0.3 μg/kg, and rocuronium 0.6 mg/kg intravenously. Assisted by a GlideScope video laryngoscope, a NIM-EMG-ETT (Shanghai Handy Medical Instrument Co., Ltd.) will be applied for intubation. The cuff pressure will be inflated to 20 cmH_2O and checked every 30 min by a manometer [12, 13]. A size of 7 mm was chosen for men, and a size of 6 mm was chosen for women. After induction, all patients will undergo ultrasound-guided iSLNB.

Intervention description {11a}

Patients in the ultrasound-guided iSLNB group will be positioned in the supine position with the neck extended and the head turned to the right side. A linear probe (6–12 MHz, Sonosite M-Turbo) will be used to perform an oblique parasagittal scan between the levels of the hyoid and thyroid cartilage. The following structures will be observed from front to back: the hyoid muscle, sternocleidomastoid muscle, thyroid muscle, thyroid membrane, superior laryngeal artery, and anterior interstices of the vocal folds. After the anatomical structures are determined, a 24-gauge needle will be inserted to penetrate the muscle over the thyroid membrane via the out-of-plane method, after which 2 ml of 0.5% ropivacaine (marked as the "experimental drug") will be injected into the thyrohyoid membrane next to the superior laryngeal artery. The same operation will be performed on the left side.

Explanation for the choice of comparators {6b}

The participants in the control group will be given 2 ml of saline (also referred to as the "experimental drug") on each side under the same conditions.

Intraoperative anaesthetic management and postoperative assessment

Anaesthesia will be maintained with propofol and remifentanil. The bispectral index will be kept between 40 and 60, and the pressure of the end-tidal carbon dioxide will be maintained between 35 and 45 mmHg. A neural integrity monitor 3.0 system (Medtronic, Minneapolis, MN, USA) will be employed for IONM, which will be carried out following the recommendations of the IONM Study Group [14, 15]. Sufentanil 5 μg will be injected intravenously at the end of the surgery. In the recovery room or ward, if participants called for a painkiller or are ranked with a visual analogue scale (VAS) score greater than 4 points, 50 mg flurbiprofen will be administered intravenously, and the total dosage within 48 h (h) will be recorded. At the same time, we will ask patients who request medication whether they need it for a sore throat or their surgical wounds. Oral suctioning will be performed only once when tracheal extubation. Three researchers will perform the anaesthesia, and four experienced surgeons will carry out the surgeries.

At 1 h, 3 h, 8 h, 24 h and 48 h after extubation, a visit will be paid to the participants. The questions to be asked are shown in Fig. 3. The follow-up will be performed by two investigators who are unaware of the group assignment.

Criteria for discontinuing or modifying allocated interventions {11b}

The participants who meet one of the following criteria will withdraw from this study: (1) participant's demand; (2) more than one attempt at intubation; (3) coughing or bucking during intubation; and (4) arytenoid cartilage dislocation or severe postoperative adverse events.

The criteria for modifying the allocated interventions include any suspected unexpected serious adverse reactions or serious adverse events (SAEs) such as nerve injury, serious allergies or the intoxication with local anaesthetics in two or more patients. In this case, the study may prematurely end or the study method may be modified at once. At the same time, all enrolled patients will be contacted by their anaesthesiologists to ensure their ability to receive timely and regular treatment.

Strategies to improve adherence to interventions {11c}

The risk of occurrence of POST is high with a NIM-EMG-ETT. Noninvasive methods, such as injection of dexamethasone or inhalation of lidocaine, do not completely alleviate POST. Moreover, anaesthesiologists and surgeons will follow-up with the participants from the day of surgery to 48 h postsurgery. In this way,

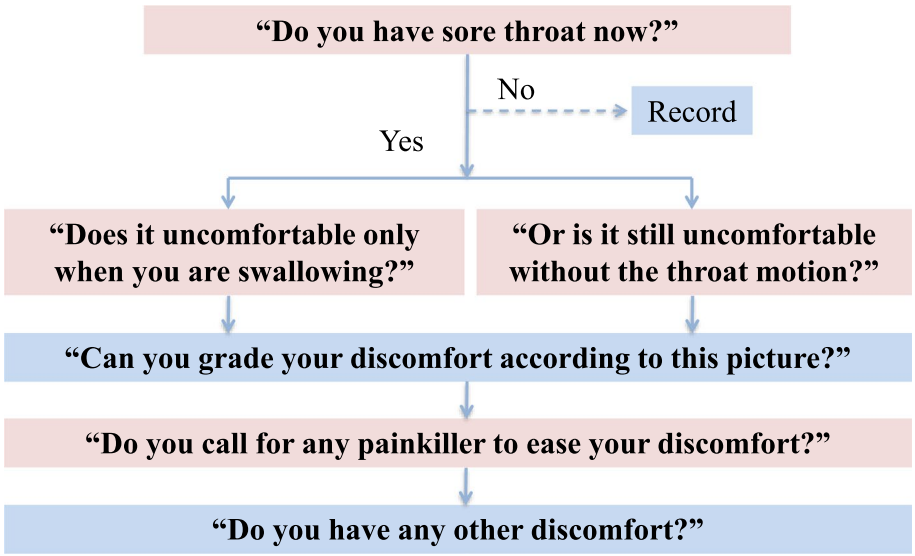

Fig. 3 Follow-up flowchart

patients taking part in this study will have close contact with their doctors. This will improve adherence to the interventions.

Relevant concomitantcare permitted or prohibited during the trial {11d}

Methods such as choosing a smaller ETT or using lubricants before intubation are not appropriate for this study. Patients enrolled in this study will receive an injection of dexamethasone during anaesthesia induction for the prevention of postoperative nausea and vomiting. If the participants provide a VAS score greater than 4 points during the postoperative follow-up, 50 mg flurbiprofen ester will be injected intravenously to reduce the pain. Other methods reported to alleviate POST will be prohibited during the trial.

Provisions for post-trial care {30}

All drugs used in this study will be used in accordance with the diagnostic and therapeutic protocols. Ultrasound-guided iSLNB has also been widely used for awake intubation. The anaesthesiologists who will perform the anaesthesia in this study are all skilled in this technique. Therefore, there will be no additional risk associated with this study compared with conventional anaesthesia. Postoperatively, patients receive the same clinical care as usual.

Outcomes {12}

The primary outcome of this study is the prevalence of POST at 24 h after extubation.

The secondary outcomes are as follows:

(1) The prevalence of POST at 1 h, 3 h, 8 h and 48 h after extubation.
(2) Severity of POST at 1 h, 3 h, 8 h, 24 h and 48 h after extubation (severity was scored as follows: Grade 0 = painless; Grade 1 = pain while swallowing; Grade 2 = continuous pain; Grade 3 = call for alleviating pain).
(3) VAS score (0–10, 0 is painless, 10 is the most severe pain) in the resting state and in the swallowing state at 1 h, 3 h, 8 h, 24 h and 48 h after extubation.
(4) Acoustic analysis: a Huawei microphone will be placed 10 cm away from the patient's mouth at a 45° angle. Then, patients will be asked to produce the vowel sounds "i" and "a" at a stable and loud pitch for 5 s. The voice data will be collected as soon as patients enter the operating room and again at 3 h and 24 h, after extubation. All of the collection will be completed in an environment with a background noise intensity of less than 50 dB. The PRAAT Program (Phonetic Sciences, University of Amsterdam) will be used to analyse a 1000-ms segment starting 800 ms from the onset of the sound [16–18].

Participant timeline {13}

The flow diagram of this study is presented in Fig. 4.

Sample size {14}

The prevalence of POST in the control group in our previous study was 89% [2]. We expect a 20% reduction in the prevalence of POST in the iSLNB group. The test statistic used is the two-sided Z-test with unpooled variance for testing two proportions with the power calculation

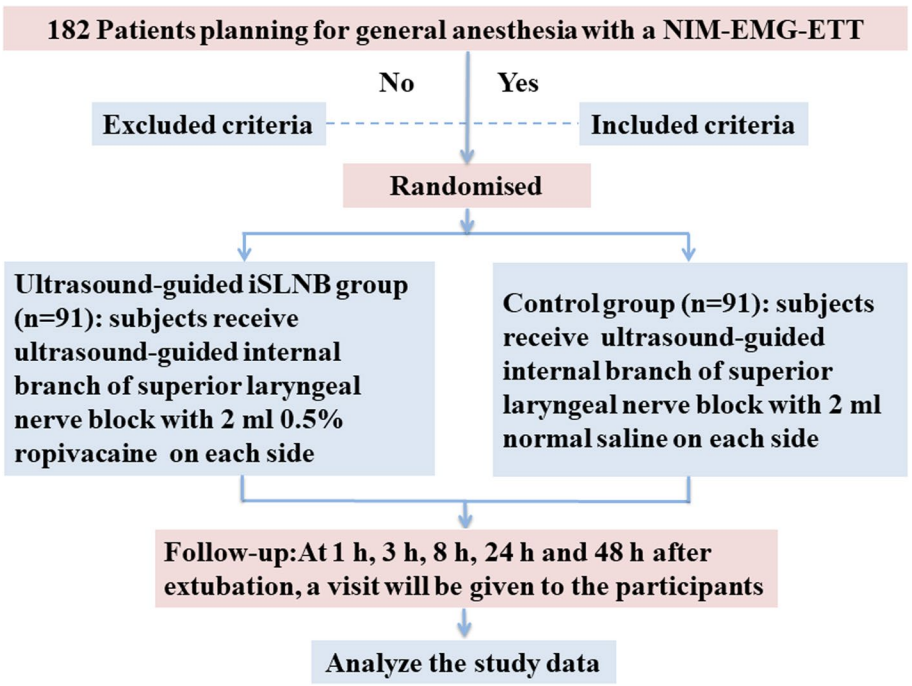

Fig. 4 The flow diagram of this study

according to normal approximation. The numeric results revealed that 82 patients for each group were required when α was set to 0.05 and the power was set to 90%, as calculated with PASS 2021. Considering a possible 10% dropout rate, it was planned for a total of 182 patients to be included.

Recruitment {15}

Patients scheduled for elective thyroidectomy with a NIM-EMG-ETT will be screened according to the inclusion and exclusion criteria when the anaesthesiologist visits the patient to discuss the anaesthesia protocol. Moreover, patients will provide informed consent once they are found to be eligible for enrolment.

Assignment of interventions: allocation

Sequence generation {16a}

The allocation sequence will be generated by computer-generated random numbers.

Concealment mechanism {16b}

The allocation sequence will be concealed in opaque sealed envelopes.

Implementation {16c}

One researcher will generate random numbers via Excel before the first participant is enrolled. After providing written informed consent, participants will be randomly assigned to either the iSLNB group or the control group at a 1:1 allocation ratio according to the random number on the screening day by the same researcher. On the day of surgery, 4 ml of 0.5% ropivacaine or 4 ml of normal saline will be prepared and marked as the "experimental drug" on the injection syringe by the same researcher. The allocation details will be concealed in an opaque envelope marked with a number in ascending rank.

Assignment of interventions: blinding

Who will be blinded {17a}

With the exception of researchers charged with implementation and supervision, patients, surgeons and medical staff (such as nurses who provide postoperative care in the postanaesthesia care unit) will all be blinded to the group allocation after assignment to interventions.

Procedure for unblinding if needed {17b}

The sealed envelope will be opened only if medically necessary or at the completion of the study.

Data collection and management

Plans for assessment and collection of outcomes {18a}

The assessment of the subjects' safety: the ASA monitor will last until the total recovery of the participant from anaesthesia. Adverse events (AEs) will be handled as soon as they are detected.

The demographic characteristics, including the age, height, weight, ASA, duration of surgery, duration of intubation (defined as the time interval from laryngoscope entry into the mouth to its withdrawal), airway pressure and collective fentanyl (including sufentanil and remifentanil used in this study) dose, will be recorded.

Plans to promote participant retention and complete follow-up {18b}

The study process and requirements will be communicated to patients in detail. The follow-up period of this study is 48 h, which is the duration of hospitalization for most patients. If the participant is absent from the hospital for any reason, a telephone follow-up can also be completed at 48 h after extubation.

Data management {19}

In addition to age, height and patient weight, two reliable phone numbers will be recorded during recruitment for follow-up. A case report form will be used to collect the subjects' data. All of the documents in this study will be stored in the department of the principal researcher.

Confidentiality {27}

All of the research data will be stored safely and confidentially with the principal researcher. All of the study documents will be referred to by the subject code. The identification code list will only be available to the principal researcher during the study and will also be safeguarded by the principal investigator after the completion of the study. The identification details of the participants will not be reported in any publication, ever.

Plans for collection, laboratory evaluation and storage of biological specimens for genetic or molecular analysis in this trial/future use {33}

Not applicable. There are no plans for collection, laboratory evaluation or storage of biological samples for genetic or molecular analysis in the current trial or for future use in ancillary studies.

Statistical methods

Statistical methods for primary and secondary outcomes {20a}

The primary outcome is a categorical variable, which will be reported as the number of patients (N) as well as percentages (%) and analysed by the chi-square test or Fisher's exact test, as appropriate. The prevalence of POST at 1 h, 3 h, 8 h and 48 h after extubation will be handled in the same manner as the primary outcomes. The severity of POST is also a categorical variable, which will be reported as the number of patients (N) and analysed by the chi-square test or Fisher's exact test, as appropriate. VAS and acoustic measurements are continuous variables, which will be summarized as the means ± standard deviations and analysed by an independent-samples t test or expressed as medians with ranges and analysed by a Kruskal–Wallis test due to the distribution and homogeneity of variance of the dataset. $P < 0.05$ will be considered statistically significant. We do not plan to have any adjustment on the main analysis. All of these tests will be conducted with SPSS 20 (SPSS Inc., Chicago, IL, USA).

Interim analyses {21b}

The trial does not have an interim analysis plan.

Methods for additional analyses (e.g. subgroup analyses) {20b}

There are no subgroup analyses planned.

Methods in analysis to handle protocol non-adherence and any statistical methods to handle missing data {20c}

Missing data due to patient withdrawal will not be included in the final data analysis. Intention-to-treat will be used to handle protocol non-adherence except for participant withdrawal, such as losing the contact of the participant. The missing data will be minimized by using the methods mentioned above. When the primary outcome is missing, multiple imputation will be used to address the missing values. When fewer than 5% of secondary outcomes are missing, we will directly delete the missing values. When more than 5% of secondary indicators are missing, we will still use multiple imputation to handle the missing values.

Plans to give access to the full protocol, participant level-data and statistical code {31c}

The full protocol, participant-level dataset and statistical code of the study are available with the corresponding author upon reasonable request. Moreover, the request must also be in agreement with the research collaboration and data transfer guidelines of Shanghai Sixth People's Hospital Affiliated with Shanghai Jiao Tong University School of Medicine.

Oversight and monitoring

Composition of the coordinating centre and trial steering committee {5d}

This is a short-term one-centre study. There is no trial steering committee of this study. All of the relevant work, including supervision of the study, medical responsibility of the patients, trial registration, coordination with surgeries, recruitment, informed consent, allocation, implications of the intervention, follow-up, data collection and data retention, will be provided by the study investigators. The researchers will meet biweekly.

Composition of the data monitoring committee, its role and reporting structure {21a}

There is no special data monitoring committee for this trial. First, our sponsor will supervise the process of the study and provide advice on the trial design. Second, although this is a blinded study, two researchers will be aware of the allocation and will unblind the study if needed. Third, the interventions, drugs and surgical methods used in this study are all regularly applied in the clinic. Therefore, there is no additional risk in this study. In the case of SAEs, researchers will record and report them to the ethics committee. Finally, the period of this study is short and there is no interim analysis.

Adverse event reporting and harms {22}

All of the AEs will be recorded accurately, completely, in a timely and legal manner, with the signature of the researcher and the recording date. An AE record form will be used to record the description of the AE and all associated symptoms, the time of occurrence, the time of termination, the degree and frequency of episodes, any given treatment, the final outcome of the AE, and whether it is related to the intervention. Nerve injury, intoxication and allergies to local aesthetics will be considered AEs according to our previous clinical practice. Once any events occur, they will be recorded as mentioned above.

Frequency and plans for auditing trial conduct {23}

The sponsor will audit the trial conduct by supervising the study procedures and looking over the original study records every 6 months.

Plans for communicating important protocol amendments to relevant parties (e.g. trial participants, ethical committees) {25}

Any amendment to the trial protocol during the course of the trial should be submitted to the ethics committee for review and approval before implementation. If there is a need to modify the study protocol, we will submit the following relevant information: (1) the content and reason for the modification; (2) the impact of the modification of the protocol on the expected risks and benefits; and (3) the impact of the modification of the protocol on the rights and safety of the subjects. The ethics committee will evaluate the risks and benefits of the trial after the modification of the protocol and provide an opinion. To avoid urgent harm to the subjects, researchers may modify the protocol before submitting it to the ethics committee for review and approval and then make a written report to the ethics committee in a timely manner.

Dissemination plans {31a}

The results of this study will be published in an international peer-reviewed online journal.

Discussion

The results of this study may provide a method to alleviate POST with a NIM-EMG-ETT. To the best of our knowledge, this is the first study to evaluate the effect of ultrasound-guided iSLNB with ropivacaine on POST caused by NIM-EMG-ETT. This may ease the discomfort patients experience in the recovery period and provide better quality of care.

Thyroidectomy always has a high incidence of POST. Swelling and mucosal irritation of the vocal cord may be the cause, which evokes nociceptive and parasympathetic impulses via the vagus nerve, triggering a sore throat after thyroidectomy [16, 19]. Several methods have been reported to ease POST [4–6]. A thinner ETT can reduce POST but also results in increased airway pressure and hypoventilation. The application of lubrication on the ETT before intubation can inhibit POST. However, lubrication, for example, betamethasone gel and topical lidocaine, may affect the conductivity of the NIM-EMG-ETT [20, 21]. Water washing has been reported to contaminate the ETT, thus resulting in infections [6].

It has been reported that SLNB can effectively suppress POST [7–9]. The superior laryngeal nerve (SLN) originates from the vagus nerve and descends posteriorly to the carotid artery towards the larynx. At the level of the hyoid bone, it is divided into external and internal branches. The internal branch of the superior laryngeal nerve (iSLN) passes immediately inferior to the greater horn of the hyoid bone. Accompanied by the superior laryngeal artery, the iSLN enters the thyrohyoid membrane under the thyrohyoid and sternohyoid muscles [10, 22, 23]. This is the location where the iSLN can be imaged together with the artery and blocked under ultrasound guidance [12]. The iSLN innervates the laryngeal mucosa above the level of the vocal cords [22]. Therefore, iSLNB can achieve an anaesthetic effect on the root of the tongue, epiglottis and mucous membrane of the larynx above the glottis fissure, thus suppressing POST and the cough reflex [7, 12]. As the iSLN is superficially located, it can be easily blocked and applied in everyday clinical practice.

Jin and colleagues demonstrated that ultrasound-guided iSLNB with dexamethasone could attenuate POST induced by a NIM-EMG-ETT tube. Moreover, they considered that "the local anaesthetics may suppress the tension of the vocal musculature and induce

dysphonia after the nerve block" [12]. Controversy exists as to whether the iSLN governs the movement of vocal fold closure [24, 25]. However, in addition to intubation, airway dryness [26] and surgical procedures can lead to postoperative voice changes [18, 27]. Therefore, acoustic analysis is necessary in this study and will provide insight into whether iSLNB with local anaesthetics affects the postoperative voice. Moreover, Jin and colleagues' study enrolled only female patients, whereas our study will include both male and female patients. Some studies have chosen lidocaine or ropivacaine at lower concentrations for iSLNB [7, 10], whereas we chose 2 ml 0.5% ropivacaine according to our experience with iSLNB for conscious endotracheal intubation.

There are some limitations in our trial. First, this is a single-centre study because of economic reasons. However, a correct evaluation sample size may help the results of this study be meaningful. Another limitation is that we chose only one type of NIM-EMG-ETT in our study. However, the conclusions of this study should be applicable to other types of NIM-EMG-ETTs according to the working mechanism.

There are also some merits to our study. First, the randomization in our trial will reduce the risk of selection bias. Second, except for the researcher in charge of allocation and supervision, all of the other researchers will remain blinded to the allocation, which can reduce the treatment effect estimate bias. Third, all of the trial processes will be performed by the investigators of this study according to the study protocol, which can avoid performance bias.

In conclusion, our study may find that iSLNB can effectively relieve POST via NIM-EMG-ETT, which is a more precise method with a faster onset, a longer duration of action and fewer complications [9].

Trial status

This is protocol version 1.0 created on January 20, 2024. This trial will be initiated in February 2024, and recruitment is planned to be completed in June 2024.

Abbreviations

POST	Postoperative sore throat
NIM-EMG-ETT	Neural integrity monitor electromyography endotracheal tube
iSLNB	Internal branch of superior laryngeal nerve block
ETT	Endotracheal tube
SLNB	Superior laryngeal nerve block
ASA	American Society of Anesthesiologists
IONM	Intraoperative neuromonitoring
VAS	Visual assessment score
h	Hour
SAE	Serious adverse event
AE	Adverse event
SLN	Superior laryngeal nerve
iSLN	Internal branch of the superior laryngeal nerve

Acknowledgements
We thank all of the participants for their commitment to this study.

Authors' contributions {31b}
AW conceived the study and will supervise the study. HZ and XL designed the study and wrote the protocol. XL has worked on trial registration as well as ethics matters. She will also be responsible for the recruitment, participant consent, randomization and blinding. HZ is in charge of coordinating with the surgeons. HZ, JY and LL will take part in the anaesthesia and collect the data. ZJ and XC will follow up and analyse the data. HZ and XL will interpret the participant data and prepare the final publication. All of the authors read and approved the final manuscript.

Authors' information
AW, HZ, ZJ, JY, XC and LL all have rich experience in ultrasound-guided nerve block. XL has performed previous studies on POST and IONM.

Funding {4}
This study will be funded by the Advanced Research Foundation of Shanghai Sixth People's Hospital Affiliated with Shanghai Jiao Tong University School of Medicine, China (grant number: ynhg202213). The funding body will provide financial support for this study, improve the design of the study and supervise the study's implications.

Data availability {29}
Six months after the end of the study, the primary data may be asked from the corresponding author on reasonable request.

Declarations

Ethics approval and consent to participate {24}
Written informed consent was obtained from all individual participants included in the study.
This study was approved by the ethical committee of Shanghai Sixth People's Hospital Affiliated with Shanghai Jiao Tong University School of Medicine, Shanghai, China (Chairperson Weiping Jia), on June 29, 2023 (2023–089).

Consent for publication {32}
Not applicable. This study protocol did not include any baseline or pilot data and details, images or videos relating to an individual person.

Competing interests {28}
The authors declare that they have no conflict of interests.

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