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# Randomised trial estimating length of endotracheal tube insertion using gestational age or nasal-tragus length in newborns: a study protocol

Abdul Razak ,[1] Maheer Faden,[1] Jameel Alghamdi,[2,3] Abdulaziz Binmanee,[4] Abdullah Hawash Alonazi,[5] Anas Hamdoun,[6] Saud Almugaiteeb,[1] Waseemoddin Patel,[1] Hamdi Katar,[2] Fabian Lora,[7] Abdullah Alismail ,[7] Adrian Lavery,[7] Ibrahim Hamama,[1] Noura Alsaleem,[1] Manal Alshaikh,[4] Lama Alrasheed,[8] Omar Aldibasi[9]

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For numbered affiliations see end of article.

**Correspondence to**
Dr Abdul Razak;
razakmdpaed@gmail.com

## ABSTRACT

**Introduction** Endotracheal tube (ETT) insertion depth estimation is important for optimal placement of ETT tip and balanced ventilation of the lungs. Various methods are available to determine the ETT insertion depth. The Neonatal Resuscitation Programme recommends the gestational age and nasal-tragus length (NTL) methods for estimating ETT insertion depth during cardiopulmonary resuscitation. However, the prospective data comparing these two methods is lacking.

**Methods and analysis** This is an open-label multi-centre randomised controlled trial, where gestational age and NTL methods will be used to determine the initial ETT insertion depth in term and preterm infants that are less than 28 days old, requiring oral intubation in the delivery room or neonatal intensive care unit (NICU).

**Sites and sample size** The trial is aimed to recruit 454 infants over 3 years across tertiary level NICUs.

**Outcomes** The primary outcome includes an optimally positioned ETT, defined as an ETT tip between the upper border of the first thoracic vertebra and the lower border of the second thoracic vertebra. The outcome is assessed by a paediatric radiologist, who will be masked to the group assignment. Secondary outcomes are malpositioned ETT tips, pneumothorax, ETT repositioning, chronic lung disease, invasive ventilation days, and death.

**Analysis** Data will be analysed using the intention-to-treat principle. The primary and categorical secondary outcomes will be compared using the $\chi^2$ test. Adjusted risk ratios of outcomes will be calculated along with 95% CIs through multivariable logistic regression analysis, including covariates deemed biologically to influence the outcomes.

**Ethics and dissemination** The study has been approved by the PNU Research Ethics Board (20-0148) and the respective ethical review boards of the participating centres. The results will be disseminated through conference meetings, social media platforms, and publications in scientific journals.

**Trial registration number** NCT04393337.

## Strengths and limitations of this study

- ELEGANT trial is an open-label, multicentre trial investigating the accuracy of two Neonatal Resuscitation Programme recommended endotracheal tube (ETT) insertion depth methods.
- Term and preterm infants requiring oral intubation in NICU or delivery room will be enrolled.
- Optimally positioned ETT is the primary outcome assessed by the blinded paediatric radiologist.
- Impractical to blind interventions and investigating only oral intubation are trial limitations.

## INTRODUCTION

Most infants are vigorous at birth, but some infants require assisted respiratory support, including positive pressure ventilation and endotracheal intubation.[1] Endotracheal intubation is a potentially life-saving measure in infants with severe hypoxia, cardiopulmonary arrest and extremely premature lungs. Endotracheal intubation is recommended when positive pressure ventilation with a face mask does not result in clinical improvement of an infant.[2] Although an endotracheal tube (ETT) is the most reliable way of providing positive-pressure breath, the critical factor determining the maximal efficacy of positive-pressure ventilation is the optimal placement of the ETT tip. ETT tip should be placed in a position that allows proportional ventilation of the lungs. A misplaced ETT tip can result in heterogeneous lung expansion, lung collapse, pneumothorax and asymmetrical surfactant distribution, which may eventually lead to chronic lung disease.[3] There are various methods available to determine the initial depth of ETT. Some of these methods are based on the infant's

birth weight,[4 5] gestational age, anthropometric measurements[6] and others include vocal cord guide[7] and digital palpation methods.[8–10]

The most used method is based on the infant's weight. In the weight-based method, so-called Tochen's formula, the ETT insertion depth in oral intubation is obtained by adding 6 cm to the infant's birth weight.[4] This method often overestimates the insertion depth in extremely preterm infants less than 28 weeks of gestational age.[11] Researchers attempted to improve the accuracy of ETT insertion depth by modifying Tochen's method from 6 cm to 5 cm plus weight. However, these modifications were not associated with statistically significant improvement in ETT tip positions.[5] Similarly, clinical trials evaluated various other methods such as the vocal cord guide method,[7] digital palpation method[8–10] and foot length method,[6] for estimating ETT insertion depth in newborn infants, but did not find promising results. A recent systematic review and meta-analysis showed that the commonly used estimation methods for ETT insertion depth are inaccurate and unreliable.[12] It also addressed the gap that the methods recommended by the Neonatal Resuscitation Programme (NRP) are not extensively studied in clinical trials.[2]

NRP recommends gestational age and nasal-tragus length (NTL) methods for estimating ETT insertion depth during cardiopulmonary resuscitation of the neonate.[2] The evidence to support these two NRP recommended methods is, however, limited. Two observational studies showed that using a gestational age to estimate ETT insertion depth improved the proportion of correctly placed ETT tips in newborns.[13 14] However, a randomised trial found no difference between gestational age and weight-based methods for estimating ETT insertion depth in newborns.[15] Similarly, observational studies report the NTL method—the distance from nasal septum tip to ear tragus+1 cm—for estimating ETT insertion depth improves the proportion of optimally placed ETT tips in neonates,[16–19] but no difference between the NTL method and weight-based method was found in a recent randomised trial.[20]

To the authors' knowledge, there is no head-to-head randomised trial that compares the two NRP recommended methods, gestational age and NTL methods, for estimating ETT insertion depth in newborns. Hence, this clinical trial is designed to determine the accuracy of two methods, gestational age and NTL methods (*intervention and control*), recommended by the eighth edition of NRP for estimating ETT insertion depth in oral intubation in term and preterm neonates requiring endotracheal intubation (*population*) in neonatal intensive care unit (NICU) or delivery room (*setting*).

## METHODS

### Trial hypothesis

To determine whether estimating ETT insertion depth using gestational age rather than NTL method results in more correctly positioned ETT tips in oral intubation.

### Trial design

This is a multi-centre randomised controlled trial primarily conducted in tertiary level NICUs in Saudi Arabia and extends to appropriate international tertiary level NICUs. The trial commenced in June 2020 and is aimed to recruit 454 infants over 3 years.

### Inclusion criteria

- Infants born between 23 weeks 0 days and 41 weeks 6 days gestational age.
- Infants less than 28 days of life.
- Infants requiring oral intubation in the delivery room or NICU.

### Exclusion criteria

- Infants with a chromosomal abnormality.
- Infants with major anomalies, including craniofacial anomalies and facial dysmorphism that may affect the NTL.
- Infants with unknown gestational age at birth.

### Primary outcome

The primary outcome is the proportion of the optimally positioned ETT on the chest X-ray. ETT is considered optimally positioned if the tip of the ETT lies between the upper border of the first thoracic vertebra (T1) and the lower border of the second thoracic vertebra (T2).

### Secondary outcomes

The secondary outcomes include

- ETT tip above the upper border of T1.
- ETT tip below the lower border of T2.
- Pneumothorax.
- ETT repositioning (advance or withdrawn) following the chest X-ray.
- Oxygen therapy at 28 days.
- Oxygen therapy or positive pressure support (include nasal cannula <2 L/min and >30% oxygen, nasal cannula >2 L/min and any oxygen, continuous positive airway pressure, and any oxygen, or invasive respiratory support and any oxygen) at 36 weeks postmenstrual age.
- Duration of invasive ventilation.
- Death before discharge.

### Trial procedures

#### Informed consent

Written consent will be obtained after the parents have been given a full verbal explanation and written description (online supplemental information 1). An explanation of the consent will be conducted with the parents in their native language. A hospital-based adult interpreter will be used wherein required. A deferred written consent (after initial verbal assent) where prior written consent is not feasible as the study does not involve additional risk or investigations to the participants and the interventions are otherwise considered as standard practice recommendations by the NRP and hospital sites.

### Trial interventions

The studied interventions in this study will be two different estimation methods for ETT insertion depth in oral intubation in neonates. The two methods are the gestational age method and the NTL method. In the gestational age method, the ETT insertion depth is obtained from the gestational age chart adapted from Kempley *et al*.[14] In the NTL method, the ETT insertion depth is calculated based on the formula—the distance from nasal septum tip to ear tragus+1 cm. The details of these two estimation methods are provided in online supplemental information 2, which also illustrates the positioning of the neonate before obtaining the chest X-ray.

### Randomisation

Eligible infants will be randomly assigned using a 1:1 ratio to the 'NTL method' or 'gestational age method'. The randomisation is stratified by gestational age at birth (<28 weeks and >28 weeks) and the participating centre. The randomisation sequence is generated by an independent researcher with a computer at the website www.sealedenvelope.com hosted by King Abdullah bin Abdulaziz University Hospital (KAAUH), Saudi Arabia. The randomised sequence is integrated into the in-built randomization module within the Research Electronic Data Capture (REDCap) system by the independent researcher. Therefore, the sequence is inaccessible to the trial investigators.

### Allocation concealment

Allocation will be concealed by incorporating the random permuted blocks of size 2 and 4 sequences within the REDCap system.

### Blinding

This will be an open-label trial. Blinding of the clinicians, nurses, and patient caregivers is impractical. However, to minimise the bias, the method used to estimate the ETT insertion depth will not be mentioned to the patient caregivers explicitly nor recorded in the patient charts. The primary outcome assessment will be blinded by masking the consultant paediatric radiologist to the group assignment. Similarly, the consultant paediatric radiologist will determine the following secondary outcomes—ETT tip above the upper border of T1, ETT tip below the lower border of T2 and pneumothorax. The trained research assistant will determine the other secondary outcomes (ETT repositioning after the X-ray, oxygen therapy at 28 days, oxygen therapy or positive pressure support at 36 weeks postmenstrual age, duration of invasive ventilation, and death before discharge).

### Structure and duration of trial

The trial aims to recruit 454 infants (see under sample size) from multiple tertiary-level NICUs over 3 years.

### Data collection

Data required for the trial will be collected from the clinical notes and radiological records using the data collection forms (online supplemental information 3). No additional laboratory or blood tests will be required.

### Early cessation

The trial steering committee will receive recommendations from the data monitoring committee if the trial requires early termination following the interim data analyses and evidence from relevant studies. The following measures were agreed to consider stopping the trial, wholly or partly (subgroups), after an interim analysis that will be conducted following enrolment of 200 participants.

1. An absolute difference of greater than or equal to 25% in the primary outcome between the study groups.
2. An absolute difference of less than 5% in the primary outcome between the study groups.
3. A rate of less than 20% in the primary outcome in either of the groups.

The purpose of the interim analysis is to evaluate the safety and futility rather than the efficacy. Therefore, no p value adjustment is proposed.

### Safety reporting

Any unexpected serious events (death, any life-threatening event, any event that will prolong the hospitalisation or any event that will result in disability) will be reported to the data safety monitoring committee. The committee will evaluate the risks versus benefits associated with the study or the study interventions. The committee may recommend early cessation depending on the interim data analyses.

### Statistics and analysis

#### Sample size

Our unpublished data showed using the NTL method for estimating ETT insertion depth in term and preterm infants result in 35% of correctly positioned ETT tips. The data is similar to the randomised[20] and non-randomised[21] studies that showed similar accuracy (32%–37%) with the NTL method for estimating ETT insertion depth. With 90% power and two-sided 5% significance, to detect an absolute increase of 15% in optimally positioned ETT tips using the gestational age method, we will require 454 participants. We calculated sample size using nQuery Advisor Sample Size Calculator V.8.3.0.0.[22]

### Statistical analysis

Data will be analysed based on the intention-to-treat principle. Univariate analyses will be performed to compare baseline demographic factors between the two groups (online supplemental information 4). A mean with standard deviation (normal data) or median with IQR (skewed data) will be obtained for continuous variables and numbers and percentages for categorical variables. Independent t-test (normal data) or Mann-Whitney U test (skewed data) for continuous variables and $\chi^2$ or Fisher exact test for categorical variables when appropriate will be used to analyse the groups. SAS V.9.4 will be used for

the conduct of all analyses. A detailed Statistical Analysis Plan will be developed before the interim analysis.

### Analysis of primary outcome

Adjusted risk ratios of a successful outcome will be calculated along with 95% CIs. Adjusted ratios will be determined using multivariable logistic regression analysis, including covariates deemed biologically to influence the primary outcome (online supplemental information 5). In addition, principles of best model practices will be followed (including assessment of collinearity among included variables) and determination of the predictive ability of the model using the area under the curve. Outcomes will be reported as shown in ghost tables in online supplemental information 6.

### Analysis of secondary outcomes

Similar analyses as above will be performed for all secondary outcomes that are categorical variables. Online supplemental information 5 lists variables included in the regression models for each secondary outcome. Outcomes will be reported as shown in ghost tables in online supplemental information 6.

## Handling missing data

Missing data will be evaluated in terms of their pattern (eg, missing completely at random, missing at random, etc). All analyses will be based on a listwise deletion approach where observation with complete values will be only considered for analysis for missing completely at random. Multiple imputation approaches will be applied for variables with missing values at random to impute the missing values using the recommended method.[23]

## Quality control and assurance

### Site initiation and training

The local research team will be trained in the protocol and the trial procedures in conjunction with the local principal investigator. They will deliver the training to the site physicians, respiratory therapists and nurses. In addition, the local research team will act as a point of contact for the primary coordinating centre (KAAUH) and troubleshoot as the need arises.

## Data collection, confidentiality and monitoring

We will use the data collection form (online supplemental information 3) to abstract data from patient medical records (either on paper or converted to a password-protected excel sheet) and will store it in locked office cabinets at participating sites or on a password-protected, encrypted USB drive. The primary study site, KAAUH, will initiate the data-sharing agreement (DSA). All the data will be entered from all participating centres into a single REDCap database, which will be managed from KAAUH once the DSA has been finalised among all centres.

## Patient and public involvement

No patient involved.

# DISCUSSION

This clinical trial comparing the gestational age and NTL methods will provide valuable data for clinicians determining the ETT insertion depth during oral endotracheal intubation. The findings from the clinical trial will also help address the knowledge gap in this research area and help update the NRP guidelines and recommendations. The study will also investigate the effect of gestational age on either of the methods. Though the trial is not powered for important respiratory outcomes, such as air leak, ventilation days, chronic lung disease, it will also provide comparative data assessing the impact of the estimation methods on these outcomes.

This trial is well powered for detecting the important differences between the gestational age and NTL methods for estimating ETT insertion depth. Given the large number of participants to study, we anticipate few challenges enrolling the study population. The two most significant challenges include the COVID-19 pandemic and less-invasive surfactant administration (LISA). COVID-19 pandemic-related restrictions have resulted in limited accessibility for physicians to discuss essential elements of the consent process and delayed ethical approval of additional centres. Nonetheless, we aim to keep up the enrolment with verbal assent and telephonic conversations with the parents. In addition, following LISA initiation, the rate of endotracheal intubation has come down in few study centres. Hence, additional centres from the USA are currently pending to be added as study centres for this study. In addition, these site recruitment efforts will focus on centres where LISA is not yet established.

# ETHICS AND DISSEMINATION

We will conduct the trial according to The Declaration of Helsinki (amended 2008) and The International Conference of Harmonization guidelines for Good Clinical Practice (E6). Our study has been approved by the PNU Research Ethics Board (20-0148) and the respective ethical review boards of the participating centres in Saudi Arabia. Additional centres will be included following the approval by the respective institutional review boards as they are currently pending approval in the USA. We will disseminate the results to the local and international neonatal community by presenting the trial findings at various paediatric and neonatal society meetings, publishing the findings in peer-reviewed journals and disseminating them through social media platforms.

**Author affiliations**
[1]Pediatrics, King Abdullah bin Abdulaziz University Hospital, Princess Nora bint Abdul Rahman University, Riyadh, Saudi Arabia
[2]Pediatrics, King Fahad Hospital, AlBaha, Saudi Arabia
[3]Pediatrics, AlBaha University, AlBaha, Saudi Arabia
[4]Pediatrics, King Faisal Specialist Hospital and Research Center, Riyadh, Saudi Arabia
[5]Pediatrics, King Fahad Medical City, Riyadh, Saudi Arabia
[6]Radiology, King Abdullah Bin Abdulaziz University Hospital, Riyadh, Saudi Arabia

[7]Cardiopulmonary Sciences, Loma Linda University, Loma Linda, California, USA
[8]Epidemiology and Biostatistics, Princess Nourah Bint Abdulrahman University, Riyadh, Saudi Arabia
[9]Biostatistics and Bioinformatics, King Abdullah International Medical Research Center, Riyadh, Saudi Arabia

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**Contributors** AR, MF, JA, HK, AB, AHA, AA, AL takes responsibility for the integrity of the data and the accuracy of the data analysis. Planning, concept and design: AR, MF. Acquisition, analysis or interpretation: AR, MF, AB, SA, WP, IH, LA, OA, MA, JA, HK, AHA, AA, AL, FL, LA, OA, AH. Drafting of the manuscript: AR, MF, AB, WP, IH, JA. Critical revision of the manuscript for important intellectual context: AR, MF, AB, NA, JA, HK, AHA, AA, FL, AL, MA, AH, SA. Statistical analysis: LA, OA. Obtaining funding: AR, MF, NA, SA. Administrative, technical or material support: AR, SA, WP, IH, MA, FL, LA, OA. Conduct, reporting and supervision: AR, MF, AB, NA, JA, HK, AHA, AA, FL, AL, OA, AH. Trial Steering Committee members AR, MF, AB, NA, SA, WP, OA. Data Safety Monitoring Committee members: Rayan Abdulrazaq Makhdom, Sameer Awad AlMehmadi, Shorouk Issa Mohammad Alwahsh. Research Trial Coordinator: MA.

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**Competing interests** None declared.

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**ORCID iDs**
Abdul Razak http://orcid.org/0000-0002-6185-3694
Abdullah Alismail http://orcid.org/0000-0002-7844-8943

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# SUPPLEMENTAL INFORMATION 1: CONSENT FORM

| **Consent To Participate In A Research Study** | الموافقة على المشاركة في دراسة بحثية |
|---|---|
| **Title :**<br>**Gestational Age versus Nasal-tragus Length for Estimating Endotracheal Tube Insertion Depth in Newborns – A Randomized Trial** | العنوان<br>عمر الحمل مقابل المسافة من شحمة الاذن للأنف لتقدير عمق إدخال أنبوب التنفس في القصبة الهوائية لدى الأطفال حديثي الولادة - تجربة معشاة. |
| **Principal Investigator:**<br>**Co-Investigators (Primary site only):** | Abdul Razak, MD<br>Maheer Faden, MD<br>Saud Almugaiteeb, BsRC<br>Waseemoddin Patel, MD<br>Ibrahim Hamama, MD,<br>Noura Alsaleem, MD, |
| **24 Hr. Phone Number:** 011-820-0000 Ext. 3526/3035 | رقم الهاتف: 011-820-0000 تحويلة رقم /30353526 |
| **Funding Source:** Nil | مصدر التمويل: لا يوجد |
| **Introduction:**<br>You are invited to take part in a research study for your baby. Please read this explanation about the study and its risks and benefits before you decide if you would like to take part. You should take as much time as you need to make your decision.<br><br>You should ask the study doctor or the study coordinator to explain anything that you do not understand and make sure that all of your questions are answered before signing this consent form. Before you make your decision, feel free to talk about this study with anyone you wish. Participation in this study is voluntary. | المقدمة:<br>يسرنا دعوتكم للمشاركة في هذه الدراسة البحثية الهامة لطفلكم. ويسعدنا الإجابة على جميع أسئلتكم أو استفساراتكم حول هذه الدراسة وذلك من قبل الطبيب أو مقدم الدراسة، لأهمية إيضاح هذه الدراسة ومخاطرها وفوائدها قبل التوقيع على نموذج الموافقة.<br><br>يرجى منكم -قبل اتخاذ القرار في المشاركة في هذه الدراسة- التمعن في قراءة المعلومات التالية وأخذ الوقت الكافي وطلب شرح أي من الاجراءات المطلوبة والتأكد من فهمها، ويتم ذلك بالتواصل مع الطبيب أو القائمين على هذه الدراسة. وقبل اتخاذ قراركم، نرجو عدم التردد في التحدث عن هذه الدراسة مع أي شخص ترغبون في التحدث معه، مع العلم بأن المشاركة في هذه الدراسة هي مشاركة تطوعية وليست اجبارية. |
| **Background and Purpose:**<br>Your baby has a breathing problem for which he/she needs a tube that is inserted into the windpipe. The breathing tube should be correctly placed in the center of | الهدف والغرض من الدراسة:<br>يعاني العديد من الأطفال من مشاكل في التنفس، ولذلك قد يحتاج أحدهم إلى أنبوب يتم ادخاله في القصبة الهوائية لمساعدته على التنفس. يجب وضع أنبوب التنفس بشكل صحيح في وسط القصبة الهوائية لضمان دخول الهواء للرئتين |

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| the windpipe to provide equal breaths to both the lungs. If the breathing tube is deeply placed, it may give breaths to only one lung, which may damage your baby's lungs. If the breathing tube is placed too high, there is a risk of breathing tubes getting dislodged. Hence, the breathing tube should be placed in the center of the windpipe to avoid the above-mentioned problems.<br><br>Various methods will guide us on how deeply the breathing tube should be inserted. Although there are many methods, the two ways recommended by the international society, the American Academy of Pediatrics, is the gestational age method (baby's age method) and nasal-tragus length (nose-ear distance method) method. In the baby's age method, the breathing tube insertion depth is obtained based on your baby's or gestational age. Baby's or gestational age is the age of the baby staying inside the mother's womb before delivery. In the nose-ear distance method, the breathing tube is inserted based on the distance between the baby's nose and the baby's ear. *Both of these methods are currently used at our center*.<br><br>We currently do not know whether the baby's age method is any better or worse than the nose-ear method. The purpose of this study is to find out which of these two methods is better. | بشكل متساوي. إذا تم وضع أنبوب التنفس بعمق، فقد يؤدي ذلك إلى التنفس من رئة واحدة فقط، مما قد يؤدي إلى تلف وضرر رئة الطفل. وإذا كان أنبوب التنفس مرتفعًا جدًا، فقد يكون هناك خطر خروج أنبوب التنفس. وبالتالي: يجب وضع أنبوب التنفس بحذر ودقة في منتصف القصبة الهوائية لتجنب المشاكل المذكورة أعلاه.<br><br>هناك العديد من الطرق التي سترشدنا حول كيفية إدخال أنبوب التنفس ومراعاة العمق المطلوب لذلك. وعلى الرغم من وجود العديد من الطرق، إلا أن الطريقتين الموصي بهما من قِبل المجتمع الدولي، والأكاديمية الأمريكية لطب الأطفال هما طريقة دراسة عمر الحمل (عمر الجنين) وطريقة دراسة طول الزنمة الأنفية (المسافة بين الأنف والأذن). في طريقة معرفة عمر الطفل، يتم الحصول على تقدير لمدى عمق إدخال أنبوب التنفس بناءً على عمر طفلك أو عمر الحمل. عمر الطفل أو الحمل هو عمر الجنين الذي يبقى خلاله داخل رحم الأم قبل الولادة.<br>أما بالنسبة لطريقة معرفة المسافة بين الأنف والأذن، يتم إدخال أنبوب التنفس على بناءً على المسافة بين أنف الطفل وأذنه، وحالياً، يتم استخدام الطريقتين فيمن قبلنا.<br><br>لا نعرف حاليًا ما إذا كانت طريقة حساب أسابيع الحمل أفضل أو أسوأ من طريقة المسافة بين الاذن والأنف، ولذلك فإن الغرض من إجراء هذه الدراسة هو تحديد أي من الطريقتين أفضل لإدخال الأنبوب في القصبة الهوائية لجميع الأطفال. |
| **Study Design:**<br>Your baby will be assessed to see whether he or she is able to participate in the study. If your baby is between 23 weeks 0 days and 41 weeks 6 days gestational age and less than 28 days and requires a breathing tube to support the breathing, then he or she may be eligible. | تصميم الدراسة:<br>سيتم تقييم طفلكم لمعرفة ما إذا كان هو أو هي قادراً على المشاركة في الدراسة. إذا كان عمر طفلكم بين 23 أسبوعًا أو 41 أسبوعًا من عمر الحمل وأقل من 28 يومًا ويتطلب أنبوبًا لدعم التنفس فسوف يكون مؤهلاً للمشاركة. |
| **What will be done:** | الإجراء: |

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| We will choose one of the methods, baby's age method or nose-ear distance method, to know how deep the breathing tube should be inserted in his/her windpipe. We will get an X-ray to check if the tube is in the right position. If the treating doctor feels the tube is not in the right position, then the doctor will adjust the tube to keep it in the right position. | سنختار إحدى الطرق سواء طريقة عمر الطفل أو طريقة مسافة أنف للأذن، لمعرفة مدى العمق المطلوب لإدخال أنبوب التنفس في القصبة الهوائية. وسنقوم بإجراء الأشعة السينية للتحقق مما إذا كان الأنبوب في الموضع الصحيح أم لا. إذا شعر الطبيب المعالج بأن الأنبوب ليس في الموضع الصحيح، فسيقوم الطبيب بضبط الأنبوب ليبقيه في الموضع الصحيح. |
| **Risks Related to Being in the Study:**<br>There are no risks per se from choosing one of the methods mentioned above. The doctors and nurses will measure the baby's vital signs during the procedure of placing the breathing tube in the windpipe. | المخاطر المتعلقة بالمشاركة في الدراسة:<br>لا توجد مخاطر بحد ذاتها في اختيار إحدى الطرق المذكورة أعلاه. وسيقوم الأطباء والاخصائيين بقياس مستمر للعلامات الحيوية للطفل أثناء إجراء وضع أنبوب التنفس في القصبة الهوائية. |
| **Benefits to Being in the Study:**<br>While we do not expect any direct benefit to your baby from this study, the information gained will help us in looking after similar babies who require breathing tubes to support their breathing. In particular, it will give us an idea of whether one of the two methods is better or similar. Our current knowledge that helps us look after your baby is largely gained from research in which parents of babies similar to yours agreed to participate in clinical studies. Should you wish to be informed of the results of the study, you may choose to add your email address, and the results will be shared with you upon the study's completion. | الفوائد المتعلقة بالمشاركة في الدراسة:<br>على الرغم من أننا لا نتوقع أي فائدة مباشرة لطفلك من هذه الدراسة، ولكن فإن المعلومات المكتسبة ستساعدنا في رعاية الأطفال المماثلين والذين يحتاجون إلى أنابيب التنفس لدعم عملية التنفس لديهم. وبالتحديد، ستعطينا هذه الدراسة فكرة عما إذا كانت إحدى الطريقتين أفضل أو متشابهة. إن معرفتنا الحالية والتي تساعدنا في الاعتناء بطفلك قد تم اكتسابها من الأبحاث التي وافق فيها آباء أطفال مشابهين لحالة طفلكم على المشاركة في الدراسات السريرية. إذا كنتم ترغبون في أن تكونوا على اطلاع بنتائج الدراسة، يمكنكم اختيار إضافة عنوان البريد الإلكتروني، وسيتم ارسال النتائج لكم عند الانتهاء من الدراسة. |
| **Voluntary Participation:**<br>We are looking for 454 infants to participate in this study. However, your participation in this study is voluntary. You may decide for your baby not to be in this study, or to be in the study now and then change your mind later. You may leave the study at any time without affecting the care your baby receives. You may withdraw your child from the study by notifying the investigator/study coordinator and contact information. | المشاركة التطوعية:<br>نحن نبحث عن 454 من الأطفال حديثي الولادة للمشاركة في هذه الدراسة. ومع ذلك، فإن مشاركتكم في هذه الدراسة تطوعية تمامًا، بمعنى يمكنكم اتخاذ القرار بأن يكون طفلكم في هذه الدراسة أم لا. كذلك يمكنكم اتخاذ قرار المشاركة في هذه الدراسة في الوقت الحالي، وفي حال تغيير رأيكم، يمكنكم الخروج من الدراسة في أي وقت دون تأثير على الرعاية التي يتلقاها طفلكم. يمكنكم ايقاف طفلكم من المشاركة الدراسة عن طريق إخطار الطبيب / منسق الدراسة وذلك عن طريق معلومات الاتصال المتاحة. |
| **Alternatives to Being in the Study**: | بدائل الوجود في الدراسة: |

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| Even if you choose not to stay or be part of the study, we will use one of the methods mentioned above to know how deep the breathing tube is inserted, as these are the standard methods recommended by the international societies. Few doctors may use other methods not mentioned here. All aspects of care for your baby will be the same if he/she does not participate in the study. | حتى إذا اخترتم عدم المشاركة في الدراسة، فسوف نستخدم إحدى الطرق المذكورة أعلاه لمعرفة وتقدير مدى عمق أنبوب التنفس حيث أن هذه هي الطرق القياسية التي أوصت بها المجتمعات الدولية. ولكن يوجد القليل من الأطباء الذين يستخدمون طرقاً أخرى غير مذكورة أعلاه. جميع جوانب الرعاية المقدمة للأطفال ستكون هي نفسها سواءا شاركوا أو لم يشاركوا في هذه الدراسة. |
| **Confidentiality:**<br>Personal Health Information<br>If you agree to join this study, the study doctor and his/her study; team will look at your baby's personal health information and collect only the information they need for the study. Personal health information is any information that could be used to identify your baby and includes:<br>● Name<br>● Date of birth<br>● New or existing medical records that includes types, dates and results of medical tests or procedures.<br><br>The study doctor will keep the information that is collected for the study in a locked and secure area for 10 years. Only the study team or the people or groups listed below will be allowed to look at your records. Your baby's participation in this study also may be recorded in his/her medical record at this hospital.<br><br>The following people may come to the hospital to look at the study records and at your baby's personal health information to check that the information collected for the study is correct and to make sure the study followed proper laws and guidelines:<br>● Representatives of the Princess Nourah Bint Abdulrahman University (and co-site hospital/university), Research Ethics Board | السرية:<br>إذا وافقت على الانضمام إلى هذه الدراسة، فسيقوم الطبيب أو المختص بهذه الدراسة وفريقهم بفحص المعلومات الصحية الشخصية لطفلكم وجمع المعلومات التي يحتاجون إليها فقط للدراسة. المعلومات الصحية الشخصية هي أي معلومات يمكن استخدامها لتحديد هوية طفلكم وتشمل:<br>● الاسم<br>● تاريخ الولادة<br>● السجلات الطبية الجديدة أو القائمة، والتي تشمل تواريخ وأنواع ونتائج الاختبارات أو الإجراءات الطبية.<br><br>سيتم الاحتفاظ بالمعلومات التي تم جمعها من أجل الدراسة بكل خصوصية وسرية من قبل الطبيب أو المختص بالدراسة لمدة لا تتجاوز 10 سنوات. يُسمح فقط لفريق الدراسة أو الأشخاص أو المجموعات المذكورة أدناه بالاطلاع على سجلاتكم. قد يتم تسجيل مشاركة طفلكم في هذه الدراسة أيضًا في سجله الطبي.<br><br>قد يأتي الأشخاص المذكورين أدناه إلى المستشفى للاطلاع على سجلات الدراسة وعلى معلومات الصحية لطفلكم وذلك للتأكد من صحة المعلومات التي تم جمعها من أجل الدراسة والتأكد من اتباع الدراسة للقوانين والإرشادات المناسبة:<br>● ممثلو جامعة الأميرة نورة بنت عبد الرحمن، مستشفى الحمادي، مدينة الملك فهد الطبية، الشئون الصحية بالحرس الوطني، مستشفى الملك فيصل التخصصي، مجلس أخلاقيات البحث. |

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| **Study Information that Does Not Identify You**<br>All information collected during this study, including your baby's personal health information, will be kept confidential and will not be shared with anyone outside the study unless required by law. Data from your baby's results (without any personal identifiers) will be sent to the research center at Princess Nourah Bint Abdulrahman University for analysis of the data.<br><br>Your baby will not be named in any reports, publications, or presentations that may come from this study. If you decide to leave the study, the information about your baby that was collected before you left the study will still be used. No new information will be collected without your permission. | دراسة المعلومات التي لا تحدد هويتك:<br>سيتم الاحتفاظ بجميع المعلومات التي تم جمعها خلال هذه الدراسة، بما في ذلك المعلومات الصحية لطفلكم، ولن تتم مشاركتها مع أي شخص خارج الدراسة ما لم يقتضي القانون خلاف ذلك. سيتم إرسال البيانات المرتبطة بنتائج طفلكم (بدون أي مُعرِّفات شخصية) إلى مركز الأبحاث بجامعة الأميرة نورة بنت عبد الرحمن / مستشفى الحمادي / مدينة الملك فهد الطبية / الشئون الصحية بالحرس الوطني / مستشفى الملك فيصل التخصصي لتحليل البيانات.<br><br>لن يتم تسمية طفلكم في أي تقارير أو منشورات أو عروض تقديمية تتم خلال هذه الدراسة. إذا قررت عدم المشاركة بعد الموافقة على بدء الدراسة، فإن المعلومات الخاصة بطفلكم والتي تم جمعها قبل قرار توقفكم عن المشاركة ستظل مستخدمة، ولن يتم جمع معلومات جديدة دون الحصول على موافقتكم. |
| **In Case Your Baby is Harmed in The Study:**<br>If your baby becomes ill, injured or harmed because of taking part in this study, he/she will receive care. The reasonable costs of such care will be covered for any injury, illness or harm that is directly a result of being in this study. In no way does signing this consent form waive your legal rights nor does it relieve the investigators, sponsors or involved institutions from their legal and professional responsibilities. You do not give up any of your legal rights by signing this consent form. | في حالة تعرض الطفل للأذى أثناء الدراسة:<br>إذا مرض الطفل أو أصيب بأذى نتيجة للاشتراك في هذه الدراسة، فسوف يتلقى الرعاية المطلوبة. وسيتم تغطية التكاليف المطلوبة لمثل هذه الرعاية لأي إصابة أو مرض أو ضرر ناتج عن هذه الدراسة مباشرة. توقيعكم على استمارة الموافقة لا تعني التنازل عن حقوقكم القانونية بأي شكل من الأشكال ولا يعفي المحققين أو الرعاة أو المؤسسات المعنية عن مسؤولياتهم القانونية والمهنية. لا يتم التخلي عن أي من حقوقكم القانونية عن طريق التوقيع على نموذج الموافقة. |
| **Expenses Associated with Participating in the Study:**<br>You will not have to pay for any of the procedures involved with this study. | المصروفات المرتبطة بالمشاركة في الدراسة:<br>لن تضطروا للدفع مقابل أي من الإجراءات التي تنطوي عليها هذه الدراسة. |
| **Conflict of Interest:**<br>All members of the research team have an interest in completing this study. Their interests should not influence your decision to participate in this study. You should not feel pressured to join this study. | تضارب المصالح:<br>جميع أعضاء فريق البحث مهتمون بإكمال هذه الدراسة. يجب ألا تؤثر اهتماماتهم على قراركم بالمشاركة في هذه الدراسة، ويجب التحرر من الضغوط للانضمام إلى هذه الدراسة. |

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| **Questions About the Study:**<br>If you have any questions, concerns or would like to speak to the study team for any reason, please contact: | أسئلة حول الدراسة:<br>إذا كانت لديك أي أسئلة أو مخاوف أو ترغبون في التحدث إلى فريق الدراسة لأي سبب، فيرجى الاتصال بالشخص المعني. |
| **Dr. Abdul Razak, MD (English speaker)**<br>Division of Neonatology, Department of Pediatrics<br>King Abdullah bin Abdulaziz University Hospital, Princess Nourah bint Abdulrahman University<br>Office 4.522, P.O.Box 47330, Riyadh, 11552<br>**Phone: (Office)** 0118203526; **(Cell)** +966560636849<br><br>**Mr. Saud Almugaiteeb (English/Arabic speaker)**<br>Head Critical Care, Respiratory Care Services<br>King Abdullah bin Abdulaziz University Hospital<br>Princess Nourah bint Abdulrahman University<br>Office 4.402, P.O.Box 47330, Riyadh, 11552<br>**Phone: (Office)** 0118203048; **(Cell)**+966568444611<br><br>**Dr. Maheer Faden, MD (English/Arabic speaker)**<br>Division of Neonatology, Department of Pediatrics<br>Office 4.446, P.O.Box 47330, Riyadh, 11552<br>**Phone: (Office)** 0118203035; **(Cell)** +966569102267 | |
| If you have any questions regarding your rights as a research participant, you may contact the **Research Office** of the Princess Nourah bint Abdulrahman University at **011-820-0000 ext. 2230**. The research ethical board is a group of people who oversee the ethical conduct of research studies. These people are not part of the study team. Everything that you discuss will be kept confidential. | إذا كان لديك أي أسئلة بخصوص حقوقكم في المشاركة في الأبحاث، يمكنك الاتصال بمكتب الأبحاث بجامعة الأميرة نورة بنت عبد الرحمن على الرقم 011-820-0000 تحويلة. 2230. والتحدث مع مجلس أخلاقيات البحث وهم مجموعة من الأشخاص الذين يشرفون على السلوك الأخلاقي للدراسات البحثية، علماً بأن هؤلاء الأشخاص ليسوا جزءًا من فريق الدراسة، وسيتم الاحتفاظ بسرية بما سيتم مناقشته معهم. |
| This study is explained to me and any questions I had, have been answered. I know that I (on behalf of my child) may leave the study at any time. | تم شرح هذه الدراسة لي بشكل كامل وتمت الإجابة على جميع الأسئلة وأعلم أنه يمكنني (نيابة عن طفلي) التوفق عن المشاركة في هذه الدراسة في أي وقت. |
| I agree for my child..... **(Print Study Participant's name)** to take part in this study. | أوافق على أن يشارك طفلي: .....(اسم المشارك في الدراسة) |
| **Name of person providing consent**: | اسم الشخص الذي قدم الموافقة: |
| **Signature:** **Date:** | التوقيع: التاريخ: |

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| **Relationship to study subject:** | **:**العلاقة بالطفل |
| **Email address (optional):** | **:(**عنوان البريد الإلكتروني (اختياري |
| You will be given a signed copy of this consent form. We will not share your email address with anyone. If you include your email address, we will send you one email at the end of the study to inform you of the results.) | ستحصل على نسخة موقعة من نموذج هذه الموافقة. لن ) نشارك عنوان بريدك الإلكتروني مع أي شخص آخر. إذا قمت بتضمين عنوان بريدك الإلكتروني، فسوف نرسل لك بريدًا .(إلكترونيًا واحدًا في نهاية الدراسة لإبلاغك بالنتائج |
| My signature means that I have explained the study to the participant named above. I have answered all questions. | توقيعي يعني بأنه تم شرح المعلومات المطلوبة للمشاركة في الدراسة المذكورة أعلاه، وأنني أجبت على جميع الأسئلة بشكل .صحيح |
| **Name of Person Obtaining Consent**: | **:**اسم الشخص الذي قدم الموافقة |
| **Signature: Date:** | **:**التوقيع: التاريخ |
| **Name of Principal Investigator:** | **:**اسم المشرف الرئيسي |
| **Signature: Date:** | **:**التوقيع: التاريخ |
| **Is participant assisted by the translator during the consent? Yes □ No □** | ؟هل تمت الترجمة لكم خلال توقيع هذه الموافقة<br>لا □<br>نعم□ |
| If YES, please complete the signature space below: | إذا كانت الإجابة بنعم، يرجى اكمال المعلومات أدناه: |
| The person signing below acted as a translator for the participant during the consent process and attests that the study as set out in this form was accurately translated and has had any questions answered. | الشخص الذي قام بالتوقيع أدناه قام بدور المترجم للمشارك أثناء عملية الموافقة وأشهد على أن الدراسة كما هى موضحة في هذا النموذج قد تمت ترجمتها بدقة وتمت الإجابة على جميع الأسئلة |
| **Print Name of Translator:** | الاسم: |
| **Signature:** | التوقيع: |
| **Date:** | التاريخ: |
| **Relationship to Participant:** | علاقته بالمريض: |
| **Language:** | **:**اللغة |

# SUPPLEMENTAL INFORMATION 2: TRIAL INTERVENTIONS

**Summary of the trial:** This study determines the accuracy of two methods, Nasal-tragus length (NTL) versus gestational age methods, recommended by the eighth edition of NRP for estimating endotracheal tube (ETT) insertion depth in newborns who require endotracheal intubation**.**

The team intubating the baby will be informed by the research team member regarding the method to estimate the ETT insertion depth in the eligible neonate. The methods include NTL and gestational age. They are as follows,

**Method 1: NTL method steps**

1. The intubating person should calculate the NTL by measuring the nasal-tragus length which is the distance between middle of the nasal septum to the tragus of the ear (Please refer to the figure 5.25 in NRP textbook, 7th edition, that shows how to measure nasal-tragus distance).
2. They should use a non-stretchable tape to measure the NTL.
3. Then 1 cm is added to the obtained NTL length to obtain the ETT insertion depth. For example, if the obtained NTL length is 6 cm, then the estimated ETT insertion depth is 7 cm (NTL+1cm=6+1=7cm).
4. After confirming successful insertion of the tube in the trachea, ETT should be secured using proper technique and approved securing device. The marking on the tube corresponds to the estimated insertion depth adjacent to the baby's lip.
    a. The centimeter marking on the side of the tube adjacent to the **baby's upper lip (lower margin) (**Please refer to the figure 5.27 in NRP textbook, 7th edition, that shows ETT adjacent to baby's upper lip**)**.

b. Use a commercial tube holder to fix the tube at the **middle** of the upper lip.

5. After taping the ETT, use a stethoscope to listen for breath sounds in both axillae and over the stomach. You should hear equal breath sounds on both sides. If the air entry is decreased on one side, slowly withdraw the tube while listening to the breath sounds on the quieter side. When the tube is correctly positioned, the breath sounds should improve and become equal. Any change in the insertion depth from the estimated ETT insertion depth should be recorded.

**Method 2: Gestational age method steps**

1. The intubating person should use the gestational age chart to estimate the ETT insertion depth (**Table 1**). For example, if a neonate is 24 weeks 5 days gestation, then the estimated ETT insertion depth is 5.5 cm.

| Gestation (weeks) | Endotracheal tube insertion depth at lips (cm) | Baby's weight (grams) |
|---|---|---|
| 23-24 | 5.5 | 500-600 |
| 24-25 | 6.0 | 700-800 |
| 27-29 | 6.5 | 900-1,000 |
| 30-32 | 7.0 | 1,100-1,400 |
| 33-34 | 7.5 | 1,500-1,800 |
| 35-37 | 8.0 | 1,900-2,400 |
| 38-40 | 8.5 | 2,500-3,100 |
| 41-43 | 9.0 | 3,200-4,200 |

**Table 1**: Gestational age chart (Adapted from Kempley ST, Moreira JW, Petrone FL. Endotracheal tube length for neonatal intubation. Resuscitation. 2008;77(3):369-373)

2. After confirming successful insertion of the tube in the trachea, ETT should be secured using proper technique and approved securing device. The marking on the tube corresponds to the estimated insertion depth adjacent to the baby's lip.

   a. The centimeter marking on the side of the tube adjacent to the **baby's upper lip (lower margin)** (Please refer to the figure 5.27 in NRP textbook, 7th edition, that shows ETT adjacent to baby's upper lip).

b. Use a commercial tube holder to fix the tube at the **middle** of the upper lip.

3. After taping the ETT, use a stethoscope to listen for breath sounds in both axillae and over the stomach. You should hear equal breath sounds on both sides. If the air entry is decreased on one side, slowly withdraw the tube while listening to the breath sounds on the quieter side. When the tube is correctly positioned, the breath sounds should improve and become equal. Any change in the insertion depth from the estimated ETT insertion depth should be recorded.

**Positioning the infant for the Chest X-ray:**

1. The anteroposterior view X-ray (chest and upper abdomen) should be obtained when the infant is in a supine position.
2. The infant's head, neck, and chest should be in the midline position.
3. The infant's head should be placed in a neutral position (i.e., neck neither flexed nor extended)
4. There should be no tension on the endotracheal tube.
5. Before obtaining the film, the investigator/research assistant should re-confirm that the endotracheal tube is secured at the estimated depth. For example, if the endotracheal tube insertion depth is determined to be 7 cm. The investigator/research assistant ensures that the endotracheal tube is still secured at 7 cm and is not displaced.

# SUPPLEMENTAL INFORMATION 3: DATA COLLECTION FORM

## DEMOGRAPHICS

**Gestational age: _____ Birth-weight: _____**

**Gender:** □ Male □ Female

**SGA**: □ Yes □ No

**Infant's local MRN number: _____**

**Study subject number: _____**

| | |
|---|---|
| **Centre** | Centre 1<br>Centre 2<br>Centre 3<br>Centre 4 |
| **Consent** | □ Standard □ Deferred |
| **Maternal hypertension** | □ Yes □ No |
| **Chorioamnionitis** (suspected or confirmed) | □ Yes □ No |
| **Caesarean section** | □ Yes □ No |
| **Antenatal steroids (complete course)** | □ Yes □ No |
| **Age at intubation (days)** | _____ days |
| **Chest compression at resuscitation** | □ Yes □ No |
| **Estimation ETT insertion depth method** | □ Gestational age chart □ Nasal-tragus length method |
| **ETT secured at an estimated depth** | □ Yes □ No |
| **ETT secured at less than estimated depth** | □ Yes □ No |
| **ETT secured at more than estimated depth** | □ Yes □ No |
| **Estimated ETT insertion depth** | _____ cm |

| | |
|---|---|
| **Secured ETT insertion depth** | _____ cm |
| **Extubation before chest X-ray** | □ Yes □ No |

**OUTCOME DATA**

| | |
|---|---|
| **ETT tip between the upper border of T1 and lower border of T2 (determined by the Pediatric radiologist)** | □ Yes □ No |
| **ETT tip above the upper border of T1 (determined by the Pediatric radiologist)** | □ Yes □ No |
| **ETT tip below the lower border of T2 (determined by the Pediatric radiologist)** | □ Yes □ No |
| **ETT repositioning following chest X-ray (determined by the trained research assistant)** | □ Yes □ No |
| **ETT advanced after the chest X-ray (determined by the trained research assistant)** | □ Yes □ No |
| **ETT withdrawn after the chest X-ray (determined by the trained research assistant)** | □ Yes □ No |
| **Pneumothorax (determined by the Pediatric radiologist)** | □ Yes □ No |
| **Oxygen therapy at 28 days (determined by the trained research assistant)** | □ Yes □ No |
| **Oxygen therapy or positive pressure support at 36 weeks post-menstrual age (only in preterm babies <32 weeks gestational age) (determined by the trained research assistant)** | □ Yes □ No |
| **Duration of invasive ventilation (in days) (determined by the trained research assistant)** | _____ days |
| **Death before discharge (determined by the trained research assistant)** | □ Yes □ No |

# SUPPLEMENTAL INFORMATION 4: COMPARISON OF BASELINE DEMOGRAPHICS

| | Gestational age method | Nasal-tragus length method | P-value |
|---|---|---|---|
| Gestational age, weeks [mean/median (SD/IQR)] | | | |
| Birth weight, grams [mean/median (SD/IQR)] | | | |
| Male Sex [n/N (%)] | | | |
| Small for gestational age < 10%ile [n/N (%)] | | | |
| Maternal hypertension [n/N (%)] | | | |
| Chorioamnionitis [n/N (%)] | | | |
| Cesarean section [n/N (%)] | | | |
| Antenatal steroids (complete course) [n/N (%)] | | | |
| Age at intubation [mean/median (SD/IQR)] | | | |
| Deferred consent [n/N (%)] | | | |
| ETT secured at an estimated depth [n/N (%)] | | | |
| ETT secured at less than estimated depth [n/N (%)] | | | |
| ETT secured at more than estimated depth [(n/N (%)] | | | |
| Difference between estimated depth and secured depth [mean/median (SD/IQR)] | | | |
| Extubation before chest X-ray [n/N (%)] | | | |
| Centre<br>Centre 1 [n/N (%)]<br>Centre 2 [n/N (%)]<br>Centre 3 [n/N (%)]<br>Centre 4 [n/N (%)]<br>Centre 5 [n/N (%)] | | | |

Note: ETT: endotracheal tube; IQR: interquartile range; SD: standard deviation

## SUPPLEMENTAL INFORMATION 5: DEMOGRAPHIC VARIABLES TO BE INCLUDED IN REGRESSION MODELS FOR EACH OUTCOME

| | **Optimal ETT position (Overall)** | **Optimal ETT position (<28 weeks GA)** | **Optimal ETT position (>28 weeks GA)** | **Death; Oxygen therapy at 28 days; Oxygen therapy at 36 weeks; Pneumothorax** |
|---|---|---|---|---|
| Gestational age | ✓ | | | ✓ |
| Male sex | | | | ✓ |
| SGA | ✓ | ✓ | ✓ | ✓ |
| Maternal hypertension | | | | ✓ |
| Chorioamnionitis | | | | ✓ |
| Antenatal steroids (complete course) | | | | ✓ |
| Centre | ✓ | ✓ | ✓ | ✓ |

Note: A variable will only be included in the regression model if P-value on univariate analysis (**Supplemental Information 4**) < 0.25

# SUPPLEMENTAL INFORMATION 6: COMPARISON OF PRIMARY AND SECONDARY OUTCOMES

| | Gestational age method | Nasal-tragus length method | Adjusted risk RR (95% C.I.) | P-value |
|---|---|---|---|---|
| Optimal ETT position<br>• Overall<br>• GA<br>o GA <28 weeks<br>o GA >28 weeks<br>• SGA status<br>o SGA infants<br>o Non-SGA infants | | | | |
| ETT tip above the upper border of T1 | | | - | |
| ETT tip below the lower border of T2 | | | - | |
| ETT repositioning following chest X-ray | | | - | |
| ETT advanced after the chest X-ray | | | - | |
| ETT withdrawn after the chest X-ray | | | - | |
| Pneumothorax | | | | |
| Oxygen therapy at 28 days | | | | |
| Oxygen therapy or positive pressure support at 36 weeks post-menstrual age (assessed in <32 weeks gestational age) | | | | |
| Duration of invasive ventilation (in days) | | | - | |
| Death before discharge | | | | |

Note: C.I.: confidence interval; ETT: endotracheal tube; IQR: interquartile range; RR: relative risk; SD: standard deviation