NHS
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Soiled airway tracheal intubation and the effectiveness of decontamination by paramedics: A randomised controlled manikin study

The SATIATED Study

- **This protocol has regard for the HRA guidance and order of content**

Version 1.0 **25th May, 2018**

RESEARCH REFERENCE NUMBERS

YASRD100

TRIAL REGISTRY NUMBER AND DATE

PROTOCOL VERSION NUMBER AND DATE

version 1.0, 25th May, 2018

SPONSOR / CO-SPONSORS / JOINT-SPONSORS

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FULL/LONG TITLE OF THE TRIAL

Soiled airway tracheal intubation and the effectiveness of decontamination by paramedics: A randomised controlled manikin study

SHORT TRIAL TITLE / ACRONYM

The SATIATED study

RESEARCH REFERENCE NUMBERS

IRAS Number: 245954

Clinical trials.gov Number:

SPONSORS Number: YASRD100

KEY TRIAL CONTACTS

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i. LIST of CONTENTS

ii. LIST OF ABBREVIATIONS

AE	Adverse Event
AR	Adverse Reaction
CI	Chief Investigator
CRF	Case Report Form
DC	Direct current
GCP	Good Clinical Practice
HCPC	Health and Care Professions Council
ICF	Informed Consent Form
ICMJE	The International Committee of Medical Journal Editors
NHS R&D	National Health Service Research & Development
PIS	Participant Information Sheet
PPE	Personal Protective Equipment
PRA	Patient Research Ambassador
RCT	Randomised Controlled Trial
REC	Research Ethics Committee
SALAD	Suction Assisted Laryngoscopy and Decontamination
SDV	Source Data Verification
SOP	Standard Operating Procedure
YAS	Yorkshire Ambulance Service NHS Trust

iii. TRIAL SUMMARY

Trial Title	Soiled airway tracheal intubation and the effectiveness of decontamination by paramedics: A randomised controlled manikin trial	
Internal ref. no. (or short title)	The SATIATED Study	
Clinical Phase	Not applicable	
Trial Design	Randomised controlled trial	
Trial Participants	HCPC registered Paramedics employed by Yorkshire Ambulance Service NHS Trust	
Planned Sample Size	154	
Follow up duration	None	
Planned Trial Period	1st July 2018 to 28th Feb 2019	
	Objectives	Outcome Measures
Primary	To determine the difference between paramedic first-pass intubation success, before and after SALAD training, in a simulated soiled airway	Difference in proportion of first-pass intubation success before and after SALAD training
Secondary	To determine the difference in time taken to achieve intubation success on the first-attempt, before and after SALAD training in a simulated soiled airway	Difference between mean time taken (in seconds) to perform a successful intubation on the first-attempt, before and after SALAD training.

iv. FUNDING AND SUPPORT IN KIND

FUNDER(S)	**FINANCIAL AND NON FINANCIALSUPPORT GIVEN**
College of Paramedics Small Research Grant	**£1250**

v. ROLE OF TRIAL SPONSOR AND FUNDER, TRIAL MANAGEMENT COMMITTEES

Yorkshire Ambulance Service NHS Trust (YAS) is the sponsor of this study as the employer of the Chief Investigator. Yorkshire Ambulance Service will undertake all sponsor responsibilities outlined the UK Policy Framework for Health and Social Care Research.

The only condition of funding is that the funder, College of Paramedics, has requested a copy of the final study report.

There will be no Trial management Committee for this study.

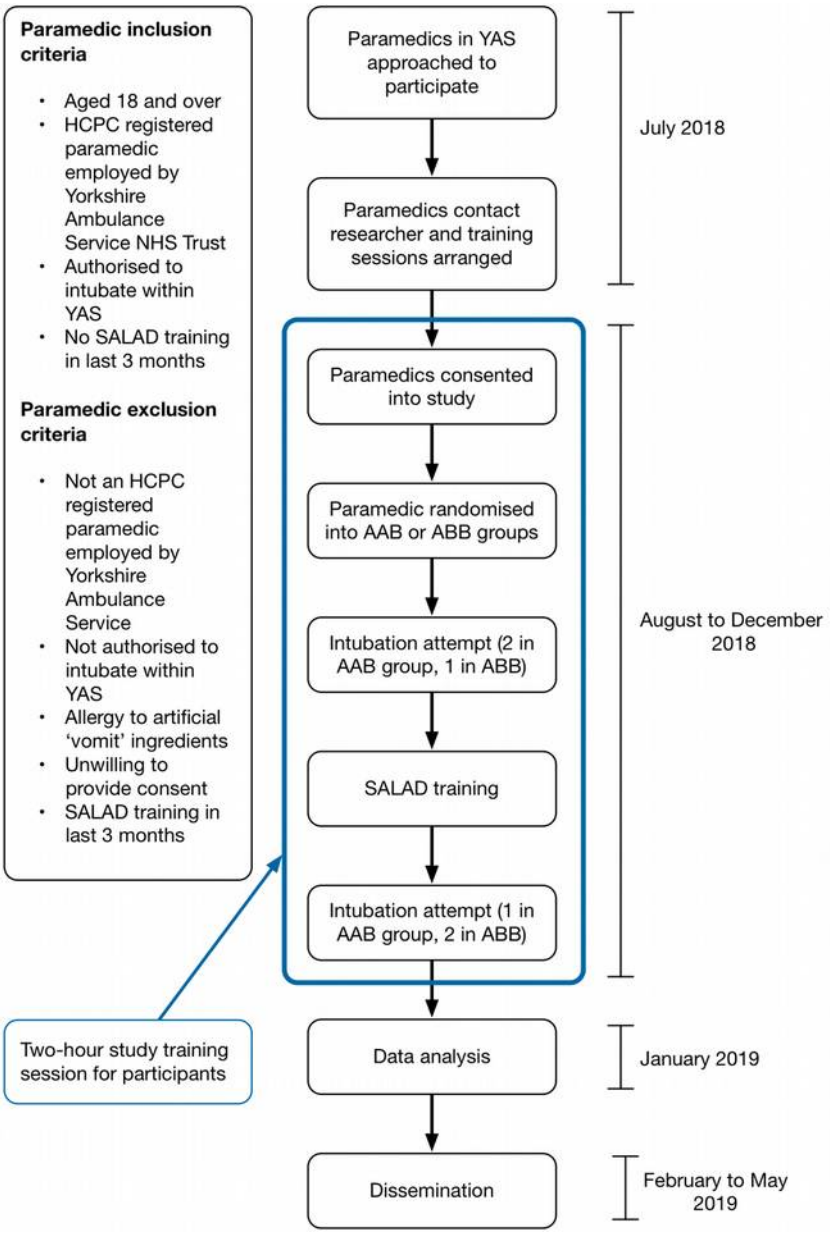
vi. Protocol contributors

Richard Pilbery and Mark Millins drafted the initial protocol. Expert input was provided by the anaesthetist who originally developed the SALAD concept, Dr. James DuCanto. Prof M. Dawn Teare provided statistical advice on sample sizing and analysis of results. A patient research ambassador (PRA) from YAS, Peter Webster, helped with plain English summaries and the dissemination strategy.

vii. KEY WORDS:

paramedic, airway management, suction assisted laryngoscopy and decontamination (SALAD), tracheal intubation

viii. TRIAL FLOW CHART



1 BACKGROUND AND RATIONALE

YAS has recently taken part in AIRWAYS-2, a randomised controlled trial, comparing the i-gel supraglottic airway device (SAD) versus tracheal intubation in the initial management of the airway in OHCA. This has provided an opportunity for closer scrutiny of advanced airway management by paramedics within the Trust, and has highlighted the challenge of intubation in the face of serious and/ or ongoing airway contamination by blood or vomit. Anecdotally, it appears that traditional suctioning and airway clearing techniques may be ineffective in this group of patients.

Vomiting and regurgitation are commonly encountered in out-hospital-cardiac arrest with a reported incidence of 20–30%.[1,2] This is of concern since patients who have suffered an OHCA, are already in extremis. If standard suctioning techniques are not sufficient to maintain a clear airway and provide ventilation, then these patients will die, irrespective of the quality of chest compressions and the timeliness of defibrillation. Arguably, tracheal intubation is the preferred airway management technique in patients with ongoing airway contamination, but there is evidence that this is difficult to achieve when the airway is soiled.[3] Even if patients survive to the hospital, it is possible that aspiration pneumonias may adversely affect survival outcome, although this has yet to be proved empirically.[4]

Traditional suctioning techniques have been criticised, and training in the management of contaminated airways, limited. This has led to the development of a combined suction/laryngoscopy technique to facilitate intubation, known as Suction Assisted Laryngoscopy and Airway Decontamination (SALAD), and the creation of modified airway manikins to allow for practice in these techniques.[5]

However, to date there has only been one study specifically looking at the SALAD technique and the outcomes were self-reported confidence measures of trainees in using the technique. Other techniques have been described to manage significant airway contamination, including the use of a meconium aspirator,[6] which is not practical in the out-of-hospital environment (and requires a device that is not typically carried by UK ambulance services), and deliberate intubation of the oesophagus (the oesophageal diversion manoeuvre), of which the sum total of evidence in support of the procedure is a single case report.[7]

Prior to undertaking clinical studies, it is important to determine the feasibility of teaching the technique to paramedics in a brief training session, and testing whether it has a beneficial effect on paramedic intubation success. Training necessarily needs to be concise given the operational demands of the ambulance service at present, which is placing training time under increasing pressure. A training programme that required a whole day to undertake, for example, would not be pragmatic to implement.

In this study, the primary outcome measure of interest is first-pass intubation success. There are

published values on non-physician first-pass intubation success, which is reported to be approximately 70%, although this is likely to be lower in soiled airways.[8] Arguably, overall intubation success could also be an indication of intubation competence, but by not allowing multiple intubation attempts at each stage of the assessment, the participants are minimally inconvenienced in terms of time required to take part in the study, while still providing an objective measurements of the effect of the training intervention.

1.1 Assessment and management of risk

This overall risk of conducting this study is low. An airway training manikin will be utilised instead of patients to enable reliable repetition of intubation attempts. All equipment used in the study is standard equipment that paramedic participants will be familiar with, including personal protective equipment (eyewear and gloves) that is available for staff to wear during an intubation attempt.

The vomiting manikin is powered by a low voltage, direct current (DC) marine battery, which is not in direct contact with the manikin at any point. No mains voltage will be used at all. The motorised suction unit utilised will be the standard battery-powered model in use by the Service.

The ingredients for the artificial 'vomit' are water, food colouring, and xanthan gum: a gluten-free edible thickener. It is unlikely that ingestion of the simulated 'vomit' will occur, but topical exposure is possible and potential participants will be asked specifically about allergy to xanthan gum and food colouring ingredients, and excluded if this is the case. Eyewear and face masks (standard PPE) will be provided to protect against exposure to 'vomit'.

2 AIMS, OBJECTIVES AND OUTCOMES

2.1 Aim and research question

This study aims to determine whether a short teaching session of the SALAD technique to paramedics, improves their ability to intubate a contaminated airway.

The research question is: Does paramedic first-pass intubation success of a simulated contaminated airway improve following training in Suction Assisted Laryngoscopy and Airway Decontamination (SALAD)?

The null hypothesis for this study is that there is no difference in paramedic first-pass intubation success rates of a simulated contaminated airway, between pre- and post-SALAD training intubation attempts.

2.2. Primary objective

To determine the difference between paramedic first-pass intubation success, before and after SALAD training, in a simulated soiled airway

2.3 Secondary objective

To determine the difference in time taken to achieve first-pass intubation success, before and after SALAD training in a simulated soiled airway, and the effect of multiple intubation attempts on success rates following SALAD training.

2.4 Primary endpoint/outcome

The primary outcome is the difference in proportions of paramedic first-pass intubation success, before and after SALAD training

2.5 Secondary endpoints/outcomes

The secondary outcomes are:

- Mean of the differences in intubation attempt times, between first and second intubation attempts, and between pre- and post-training attempts
- Difference in success rates between participants who have two post-training intubation attempts versus participants who only have one post-training intubation attempt.

3 TRIAL DESIGN

The trial has been designed as a randomised controlled trial (RCT), with the primary objective of determining whether first-past intubation success rates are higher in the post-SALAD training group of participants. In order to adjust for changes in participant performance by making repeated attempts at intubation, paramedics will be randomised into either: making two pre-training intubation attempts and one post-training attempt (AAB); or making one pre-training intubation attempt and two post-training attempts (ABB).

4 TRIAL SETTING

This study will be conducted at a single site (YAS). All sessions will be conducted on Trust premises, typically ambulance stations or other training facilities around the Trust, which are geographically convenient for participants to attend. Participants will be NHS staff who are employed by YAS, and who are Health and Care Professions Council (HCPC) registered paramedics.

5 PARTICIPANT ELIGIBILITY CRITERIA

5.1 Inclusion criteria

- Aged 18 and over
- HCPC registered paramedic employed by Yorkshire Ambulance Service
- Authorised to intubate within Yorkshire Ambulance Service
- No SALAD training in the last 3 months

5.2 Exclusion criteria

- Not an HCPC registered paramedic employed by Yorkshire Ambulance Service
- Not authorised to intubate within Yorkshire Ambulance Service
- Allergy to artificial 'vomit' ingredients
- Unwilling to provide consent
- SALAD training in the last 3 months

6 TRIAL PROCEDURES

6.1 Recruitment

Potential participants will be invited indirectly to participate via Trust email and the weekly operational update that is widely distributed throughout the Trust. This will include simultaneous distribution of the PIS via the same route.

Paramedics who are interested in the study will be asked to contact the CI to arrange attendance at a study training session. The CI will confirm that the potential participant is an operational paramedic working for the Trust, and is not allergic to the 'vomit' ingredients. This will be documented on a spreadsheet of potential participants.

All participants will have their travel mileage refunded at a rate of 45p/mile.

6.2 Consent

All participants will have capacity as they are operational paramedics and employees of Yorkshire Ambulance Service NHS Trust. At the start of the study training session, informed consent will be obtained by the CI and verified by completion of a signed consent form.

6.3 Withdrawal criteria

Participants can withdraw from the trial at any time and do not have to provide justification for doing so, by contacting the CI for the trial. Details of the withdrawal will be entered onto the CRF. Participants who withdraw, can request that any non-anonymised data is erased.

Since the sample size is required to ensure the study is adequately powered, additional paramedic participants will be recruited, if necessary, to offset any withdrawals. For the same reason, this study will continue until the sample size has been reached.

7 INTERVENTION UNDER STUDY

7.1 SALAD manikin

The manikin to be used in the study is a modified TruCorp AirSim Advance, which has realistic airway anatomy and can be used for tracheal intubation training. The oesophagus of this manikin has been connected, via a hosepipe, to a bilge pump that is sited within a reservoir of simulated vomit. The vomit is water, coloured with food-grade colouring, and thickened with xanthan gum (a food additive). Once the bilge pump is switched on, it can generate a constant flow of liquid into the oropharynx, obscuring any view of the laryngeal inlet. The flow rate is controlled by a tap, which will be calibrated to provide 1 L/min of vomit to the oropharynx of the manikin during the intubation attempts. To keep vomit within the oropharynx, the left and right bronchi on the manikin have been occluded.

An endoscope camera will be placed in the posterior oropharynx after each intubation attempt and connected to a laptop, to provide a view of the vocal cords for the researcher, but not the participant, allowing confirmation of correct tube placement, while not obstructing the view of the paramedic participant attempting direct laryngoscopy.

Standard intubation equipment, including personal protective equipment (PPE) and motorised suction, that is routinely used within YAS will be provided for participants, and the study researcher will act as a competent assistant for the intubation attempts.

7.2 Procedure

Informed consent will be obtained from paramedic participants prior to commencing the study. They will then be randomised to determine the order in which they will attempt intubation, and whether they will make two pre-training and one post-training attempts (AAB group), or one pre-training and two post-training attempts (ABB group). All attempts will utilise direct laryngoscopy, which is the standard intubation technique within YAS. Prior to each intubation attempt, the manikin will be primed with vomit. Once the oropharynx is full, the participant will undertake their first intubation attempt. The manikin will deliver vomit to the oropharynx at a rate of 1L/min.

All intubation attempts will be video recorded to allow for accurate time-keeping, since the researcher

will be assisting the paramedic with their intubation attempt. However, the researcher will also time the intubation attempt using a stopwatch to record the time, in the event that a video recording fails. Participants will be deemed to have begun their intubation attempt once pump which makes the manikin vomit, is turned on. The attempt will be considered over when:

- The paramedic who has intubated the manikin verbally confirms with the researcher that the attempt has been completed or;
- 90 seconds has elapsed or;
- The tracheal tube is placed into the oesophagus and the cuff is inflated while the pump is still running.

If the tracheal tube is not in the trachea, with the cuff inflated and connected to a bag-valve device within 90 seconds, the attempt will be considered a failure.

Participants randomised to the two pre-training attempts (AAB) will make a second intubation attempt prior to the group training session. Once all participants have completed their pre-training intubation attempt, the training session will be delivered, and will take around 45 minutes to complete, including time for participant practice. The training intervention will adopt the Advanced Life Support Group/Resuscitation Council 4-stage approach of skills teaching, and is comprised of:[9]

1. A real-time demonstration of the SALAD technique by the researcher
2. A repeated demonstration with an explanation of the rationale of the steps taken when performing SALAD (not real-time)
3. Another demonstration of the SALAD technique conducted by the researcher, but guided by one of the participants
4. An attempt by the same participant who guided the researcher in the previous step, followed by a practice attempt by the other participants.

Following the training session, participants will make their post-training intubation attempt(s). This will be conducted using the same method as for the pre-training intubation attempt(s). Participants randomised into the two post-training attempts (ABB), will make their second attempt immediately following the first post-training attempt.

8 STATISTICS AND DATA ANALYSIS

8.1 Sample size calculation

The null hypothesis (H_0) for this study is that the training intervention will have no effect on participant intubation success. The alternative hypothesis (H_1) is that intubation success will change following the training intervention.

A sample size of 154 participants is required to determine a change in the proportion of intubation success, from 0.25 in the pre-training group, to 0.50 in post-training group, with a power (1-β) of 90% and a significance level (α) of 5%. Given that there is no literature to guide expected performance, a conservative estimate has been made in consultation with an internationally recognised SALAD expert, Dr. James DuCanto (J.DuCanto, personal communication, April 26, 2018).

The sample size calculation was determined by using the application G*Power, version 3.1, using the parameters and test shown in Figure 1. No subgroup analyses or adjustment of the analysis to account for the demographic data obtained from participants will be undertaken.

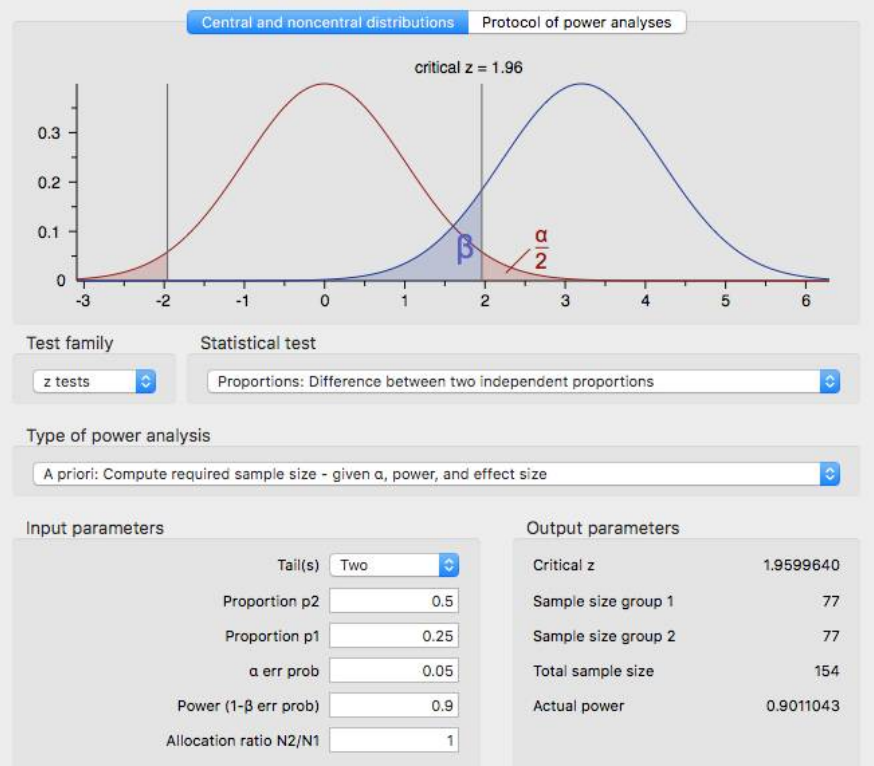


Figure 1: G*Power parameters for study sample size calculation

8.2 Planned recruitment rate

Recruitment is planned to occur between July and December, 2018 with 6–8 sessions per month comprised of 3–6 participants per session.

8.3 Statistical analysis plan

8.3.1 Summary of baseline data and flow of patients

Descriptive statistics will be used to summarise the demographic data provided by participants. The order pathway that participants make their intubation attempts (AAB or ABB) will be 1:1 randomised, using a block randomisation sequence provided by RANDOM.ORG. In addition, block randomisation will be utilised to allocate participants into either the AAB or ABB group. To distinguish between the training pathways and number of the assessed attempts, we will use $A_{01}A_{02}B_{01}$ and $A_{11}B_{11}B_{12}$ to differentiate between groups and attempts.

8.3.2 Primary outcome analysis

To determine if the training has an effect and increases the success rate of intubation, we will compare the proportions of success in the groups who receive no training before their 2nd intubation attempt (A_{02}), with those who do receive training before their 2nd intubation attempt (B_{11}). Comparing the rates at these time points, controls for any learning effect due to participants making more than one attempt at intubation. The difference in the two proportions will be analysed using a two independent samples proportion z-test. We will assume a two-sided type 1 error rate of 5%, and report the proportions and the difference in the proportions along with 95% confidence intervals.

8.3.3 Secondary outcome analysis

Intubation times will be truncated at 90 seconds. We will compare the mean of the differences ($A_{01} – A_{02}$) with the mean of differences ($A_{11} – B_{11}$). We will also compare the mean of the differences seen at the final measurements, ($A_{01} – B_{01}$) and ($A_{11} – B_{12}$), to see if there are differences between the two pathways, which might suggest that practice following the training, further improves the time to successful intubation. In addition, we will also compare the success rates between B_{01} and B_{02} to see whether practice following training improves intubation success rate. A Student's t-test will be utilised to test for the differences between mean pre- and post-training intubation attempt times. The difference in success rates, will be analysed using a two independent samples proportion z-test. We will assume a two-sided type 1 error rate of 5%, and report the proportions and the difference in the proportions along with 95% confidence intervals.

8.4 Procedure(s) to account for missing or spurious data

In the event that the video recording cannot be used to determine intubation success and time to success, the researcher recorded outcomes will be utilised instead. Should a participant not complete all three attempts, then their data will not be included in the final analysis and a replacement participant sought to ensure that the target sample size is achieved.

9 DATA MANAGEMENT

9.1 Data collection tools and source document identification

The source data for the study will consist of a custom case report form and video recordings.

9.2 Data handling and record keeping

The CRF will be completed by the CI during the participant attempts. This will include the basic demographic data, whether the first-pass intubation is successful, if the tube was suctioned prior to an attempt at ventilation, and the time taken to intubate.

To minimise the chance of missing data, participants will be advised that the will not be able to participate in the study if they do not know how many intubations they have performed in the preceding 12 months, or if they have received training in SALAD in the past 3 months. In addition, although the most accurate time to intubate will be available from the video, the CI will also have a stopwatch to record the time in case of video failure.

To maintain participant confidentiality, the CRF will not contain any personal-identifiable data. Instead, the participant will be identified by a unique study ID.

Video recordings of the training sessions will be held securely on a Trust computer which only the researcher can access. Once timings and confirmation of intubation success have been determined following review of the video, the recording will be erased (within one week, typically). Participants will not be identifiable from the data produced by the trial.

All CRFs will be securely stored on Trust premises in a locked cabinet, within a secure room.

9.3 Access to Data

Direct access will be granted to authorised representatives from the Sponsor, host institution and the regulatory authorities to permit trial-related monitoring, audits and inspections in line with participant consent.

9.4 Archiving

Archiving will be authorised by the Sponsor following submission of the end of trial report. All source documentation will be archived on Trust premises in a locked cabinet in a secure location. Video recordings will not be archived as they will be securely erased during the study.

Data will be available for future analysis for a period of 2 years prior to being archived. All essential documents will be archived for a minimum of 5 years after completion of trial. Destruction of essential documents will require authorisation from the Sponsor.

10 MONITORING, AUDIT & INSPECTION

The study may be audited as part of the routine audit process as laid out in the Sponsors Research Governance Policy. All source documents and essential documents will be available to the sponsor for audit for at least five years.

11 ETHICAL AND REGULATORY CONSIDERATIONS

11.1 Research Ethics Committee (REC) review and reports

Prior to the start of the trial, approval will be sought from a REC for the trial protocol, informed consent forms and other relevant documents. Substantial amendments that require review by REC will not be implemented until the REC grants a favourable opinion for the trial, and all correspondence with the REC will be retained in the Trial Master File. If the trial is ended prematurely, the Chief Investigator will notify the REC, including the reasons for the premature termination.

11.2 Peer review

Peer review has been provided as part of the funding application process and was proportionate, independent and expert.

11.3 Public and Patient Involvement

YAS is fortunate to have a Patient Research Ambassador (PRA) who has been involved in the production of lay summaries and sense-checking of documents, in addition to advising on the proposed dissemination plan.

11.3 Protocol compliance

Any breach of protocol will be reported via the YAS Datix system to notify the Research and Development department at YAS. Duty of Candour will be considered in consultation with the YAS Duty of Candour specialist.

11.4 Data protection and participant confidentiality

All investigators and trial site staff will comply with the requirements of the Data Protection Act 1998/General Data Protection Regulations 2018 (whichever is in force at the time of the study being undertaken) with regards to the collection, storage, processing and disclosure of personal information..

Each participant will be allocated a participant ID once informed consent has been obtained. This will be used on all study source documents. Access to the source documents will be restricted to YAS research and development (R&D) personnel only. Video recordings will only be accessible by the CI, the data custodian.

Video recordings of the training sessions will be held securely on a Trust computer which only the CI can access. Once timings and confirmation of intubation success have been determined following review of the video, the recording will be securely erased. Participants will not be identifiable from the data produced by the trial. All CRFs will be securely stored on Trust premises in a locked cabinet, within a secure room.

An anonymised version of the dataset will be made available for other researchers.

11.5 Financial and other competing interests for the chief investigator, PIs at each site and committee members for the overall trial management

The chief investigator has no financial or other competing interests that might influence the trial design, conduct or reporting. The technique that is the focus of this trial is not 'owned' and the equipment used is standard issue to Trust paramedics.

11.6 Indemnity

The study sponsor will assume all liability for the study activities.

11.7 Amendments

Any amendments to the protocol will be submitted to the HRA for categorisation and consideration as appropriate.

11.8 Access to the final trial dataset

The chief investigator and the statistician will be the only personnel to have access to the full dataset for the purposes of this study analysis.

12 DISSEMINATION POLICY

12.1 Dissemination policy

The results of the study will be published in a peer-reviewed journal such as the British Paramedic Journal and presented at relevant conferences such as the College of Paramedics national conference, 999 EMS Research forum and EMS2019. In addition, plain English summaries will be published in the College of Paramedics newsletter and free ambulance magazines, which are routinely

posted to all ambulance stations in the UK. A summary report will be presented to the participants and YAS, and will be available on the study website (https://satiated.ambulanceresearch.co.uk). Finally, the ubiquity of social-media will be utilised to highlight the publication of the study on Twitter, Facebook and other social media outlets.

12.2 Authorship eligibility guidelines and any intended use of professional writers

Since part of the dissemination strategy involves publishing in peer-reviewed journals, author eligibility will be determined in according with The International Committee of Medical Journal Editors (ICMJE) authorship criteria. Professional writers will not be used.

13 REFERENCES

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14. APPENDICES

14.1 Appendix 1 – Amendment History

Amendment No.	Protocol version no.	Date issued	Author(s) of changes	Details of changes made