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Paramedic management of an airway obstructed with fluid using the SALAD technique

Submission date
03/06/2019

Recruitment status
No longer recruiting

Registration date
06/06/2019

Overall study status
Completed

Last Edited
15/08/2022

Condition category
Respiratory

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
In more than one-in-five cases of out-of-hospital cardiac arrest, airways are blocked by vomit and blood. Sometimes, paramedics cannot clear the airway using methods they have been taught. If the airway cannot be cleared, the patient will die. Usually, these patients will have a breathing tube placed into their windpipe (intubation), as this provides protection from vomit and blood. To do this, the paramedic needs to be able to see the entrance to the windpipe. A new method of clearing the airway called SALAD has been used in patients to help insert a breathing tube, but it is not known whether the method can help paramedics. This study will use a manikin to see if paramedics can insert a breathing tube more often on their first attempt, using SALAD.

Who can participate?
Paramedics employed by North East Ambulance Service NHS Trust

What does the study involve?
The study involves paramedics being tested on their ability to secure the airway of a simulated patient (manikin) when the airway is full of fluid. The paramedics are then trained on a technique (SALAD) to deal with this type of situation and then tested again to see if their abilities improve. Participants are randomly allocated to make either one or two attempts before the training session on the SALAD technique, or one or two attempts after. All attempts are filmed to ensure accurate time-keeping. Participants have additional practice attempts at intubation during the training session.

What are the possible benefits and risks of participating?
The paramedics will learn and practice a technique that will hopefully allow them to better deal with a patient who has an airway that is full of fluid which would be beneficial if that situation arose. There are no risks to participating.

Where is the study run from?
North East Ambulance Service NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
April 2019 to December 2019

Who is funding the study?
SSCOR, Inc.

Who is the main contact?
Dr Graham McClelland
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
42102

Study information

Scientific Title
Soiled airway tracheal intubation and the effectiveness of decontamination by North East paramedics: a randomised controlled manikin study

Acronym

SATIATED2

Study objectives
Does training in the Suction Assisted Laryngoscopy and Airway Decontamination (SALAD) technique improve the
ability of paramedics to successfully insert a breathing tube (intubation) into the windpipe of a manikin which is
vomiting?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval is not necessary for this study as it is staff based

Study design
Randomised; Interventional; Design type: Process of Care, Education or Self-Management

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Soiled airway tracheal intubation

Interventions
Paramedics who wish to take part in the trial will contact the researcher to arrange attendance at a study training session. When a paramedic participant attends, they will be asked to give informed consent by completing the study consent form. In addition, to take account of learning that might occur by making multiple intubation attempts, participants will be randomised into one of two groups: AAB, where they will have two pre-training intubation attempts, and one post-training attempts; or ABB, where they will have one pre-training intubation attempt, and two post-training attempts.

Prior to each intubation attempt, the manikin will be primed with vomit. Once the mouth is full of vomit, the participant will undertake their first intubation attempt. The manikin will then deliver vomit to the mouth at a rate of one litre per minute. 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. An intubation attempt will start when the researcher turns on the pump to make the manikin vomit. The attempt will be considered over when any of the following occur: the paramedic who has intubated the manikin tells the researcher that the attempt has been completed; 90 seconds has passed; the breathing tube is placed into the gullet and the balloon at the end of the breathing tube is inflated while the pump is still running. If the breathing tube is not in the windpipe, with the breathing tube cuff inflated and connected to a bagvalve device within 90 seconds, the attempt will be considered a failure.
Once all participants have completed their pre-training intubation attempt(s), 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:

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 realtime)
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).

Intervention Type
Behavioural

Primary outcome(s)
Difference in proportions of paramedic intubation success before and after training

Key secondary outcome(s))
1. Mean of the differences in intubation attempt times (measured in seconds) between first and second intubation attempts and between pre- and post-training attempts
2. Difference in success rates between participants who have two post-training intubation attempts versus participants who only have one post-training intubation attempt
3. Comparison of SATIATED2 and SATIATED outcomes

Completion date
01/12/2019

Eligibility

Key inclusion criteria
1. Aged 18 and over
2. HCPC registered paramedic employed by NEAS
3. Authorised to intubate within NEAS
4. No SALAD training in the last 3 months

Participant type(s)
Health professional

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
102

Key exclusion criteria
1. Not an HCPC registered paramedic employed by NEAS
2. Not authorised to intubate within NEAS
3. Allergy to artificial ‘vomit’ ingredients
4. Unwilling to provide consent
5. SALAD training in the last 3 months

Date of first enrolment
06/08/2019

Date of final enrolment
01/12/2019

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
North East Ambulance Service NHS Foundation Trust
Benicia House
Goldcrest Way
Newburn Riverside
Newcastle Upon Tyne
United Kingdom
NE15 8NY

Sponsor information

Organisation
North East Ambulance Service NHS Foundation Trust

ROR
https://ror.org/02mphet60

Funder(s)

Funder type

Industry

Funder Name
SSCOR, Inc.

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary
Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	17/07/2020	05/01/2021	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file	version 3	08/04/2019	15/08/2022	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes