IRAS ID: 245954

Yorkshire Ambulance Service NHS Trust

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

Before you decide to take part in this study, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Feel free to ask if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

What is the purpose of the study?

Vomiting and regurgitation are commonly encountered in out-hospital-cardiac arrest with a reported incidence of 20–30%. In addition, there is some concern that standard suctioning techniques are not sufficient to maintain a clear airway and provide ventilation. 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. This study aims to determine whether a short teaching session of the SALAD technique to paramedics, improves their ability to intubate a contaminated airway on their first attempt.

Why have I been chosen?

You have been contacted to take part in this study as you are a paramedic employed by Yorkshire Ambulance Service NHS Trust.

Do I have to take part?

No. It is up to you to decide if you wish to participate. If you do decide to take part you can still withdraw at any time and you do not have to give a reason.

What will happen to me if I take part?

You will be invited to attend a study training session, which will take approximately two-hours. You will be asked to give your informed consent to take part in the study, and answer the following four questions:

1. How many intubation attempts have been recorded in your airway log in the past 12 months, and how many were successful?
2. How many years you have been qualified as a paramedic?
3. Are you familiar with the SALAD technique?
4. Have you used the SALAD technique (simulated or in clinical practice) in the past 3 months?

During the training session, you will be asked to make three attempts at intubating a specially adapted manikin which will simulate a vomiting patient. You will be 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 will be filmed to ensure accurate time-keeping. You will have additional practice attempts at intubation during the training session.

What are the possible disadvantages and risks of taking part?

It is not anticipated that you will experience any disadvantage in taking part in the study, although you will need to give up two hours of your own time, which will be unpaid (although mileage costs will be paid at 45p/mile).

What are the possible benefits of taking part?

Attending a training session will provide you with an opportunity to practice tracheal intubation, and all attempts can be added to your airway log. You will also receive a CPD certificate for attending the session.

What if something goes wrong?

Should you be unhappy about an aspect of this study and the matter is not resolved with the researcher, please email the study sponsor representative, Jane Shewan (jane.shewan1@nhs.net).

How will the data collected for this research project be used?

Yorkshire Ambulance Service NHS Trust is the sponsor for this study based in England. We will be using information from you in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. Yorkshire Ambulance Service NHS Trust will keep identifiable information about you for less than 3 months after the study has finished, with the exception of the video recordings, which will be erased as soon as the timing data has been captured.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

Direct access to the data 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. You can find out more about how we use your information by contacting yas.research@nhs.net. If you give informed consent, an anonymised version of the dataset will be made available for use in future projects.

What will happen to the results of the research project?

The results of this study will be published as widely as possible in peer-reviewed journals, pre-hospital and emergency conferences and via plain-English summaries in free publications that are delivered to ambulance stations. If you wish to receive a copy of the summary report, you can provide your email address on the consent form

Who is organising and funding the research?

The research is being conducted by Richard Pilbery, a research paramedic at YAS, and is funded by the College of Paramedics and YAS.

Who has ethically reviewed the project?

This study has been approved by an NHS Health Research Authority

For further information, please contact the researcher:
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This information sheet and consent form are available to download on the study website (https://satiated.ambulanceresearch.co.uk)