Nominated Consultee Information Sheet

Study title: Ventilator Aspiration with PneuX

Full study title: A single centre, open-label, feasibility randomised controlled trial to evaluate gastric microaspiration in critically ill patients intubated using the Venner PneuX system compared to standard care using pepsin biomarker (VAP-X)

Part 1

Introduction

Patients who are in intensive care need lifesaving treatments quickly. This means that sometimes we don't have time to discuss a research study with the patient's relatives before going ahead with these treatments. Your patient's serious condition means that they are too unwell right now to decide for themselves whether they would like to take part in this study. We have been given approval by a Research Ethics Committee to enroll patients into our study without getting their consent beforehand. Your patient has been enrolled as a participant in our research study.

Because your patient can't give consent themselves, we are asking you to advise on whether the patient should continue to take part in this study, and if you feel that he/she would be content to take part. Before you decide 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. The Critical Care Research Team will be available to go through the information sheet with you and answer any questions you may have.

What is the purpose of this study?

Patients who are so unwell that they require intensive care treatment often need support with their breathing. For this, patients have a breathing tube placed in their mouth, into their throat, and are then placed on a breathing machine (called a ventilator).

We normally protect our lungs by coughing and swallowing. This stops saliva and mucus from our mouth and stomach going into our lungs which can cause damage and lead to a chest infection (also called pneumonia). When patients need a breathing tube in intensive care, they can't cough and swallow normally which puts them at more risk of getting a chest infection. This can lead to the patient becoming more ill and, in some cases, it can lead to death.

Breathing tubes are made in a way to reduce saliva and mucus entering the lung. However, recent studies have shown that some material still enters the lung with the tubes that we already use.

There is now a newer breathing tube that shows promise in preventing mucus and saliva entering the lungs from the mouth and stomach. The new tube has already been shown to be safe and it is a licensed medical device which is already used on some patients in the NHS. This tube is called the PneuX Endotracheal Tube. We want to gather information to see whether the new tube reduces the amount of saliva and mucus entering the lung compared to the tubes we already use.

Half of the patients who enter our study will get the new tube and the other half will get the tube we already use in the hospital. The decision will be made at random and can't be influenced by anyone involved in the study or the patient's care. Doctors and nurses who are part of the study will then use some laboratory tests to see whether saliva and mucus from the mouth and stomach have entered the patient's lungs.

This study is the first small study of 50 patients. We want to know how well the study works in real life so that we can design a future larger study which we hope will tell us which breathing tube is better for our patients.

Why has my patient been chosen to participate in the study?

Your patient was chosen because they needed breathing support in the Intensive Care Unit to help them through their current illness and matched the list of requirements which made them right for our study.

Does my patient have to continue to take part in the study?

Your patient's involvement in the study is completely voluntary. It is up to you to decide whether or not you think they would have any objections to taking part in the study.

The Critical Care Research Team will be available to go through this information sheet with you and answer any questions you may have. If after reading the information sheet you think that your patient would have no objection to continuing to take part in the study we will ask you to sign a **Nominated Consultee Declaration Form**. If you change your mind at any point and believe that your patient would not want to continue taking part in the study anymore, you can withdraw them from the study.

If after reading the information sheet you think that your patient would not want to continue their participation in the study, they don't have to. It will not affect the standard of care that they receive in any way.

If your patient becomes well enough at any point, we will discuss the study with them in the same manner as we are discussing it with you, and provide them with the same information. They will then be able to decide for themselves whether or not they wish to continue with all or some parts of the study. Again, this will not affect the standard of care that they receive in any way.

If you or the patient decide to not take part in the study, we will stop collecting any more information from them. We will use information already gathered up to the point the patient leaves the study.

What will happen to my patient if they continue to participate in the study?

Your patient was fairly put into one of two groups using 50/50 random chance. This means they will have the new breathing tube (PneuX) or the current breathing tube (Taperguard).

By continuing in the study we will continue to collect samples and information about your patient.

Two samples will be taken as follows:

1. Firstly, a sample of fluid is taken from the lungs above and below the breathing tube, to test for material that has come from the mouth and stomach. The samples are normally taken from patients in the Intensive Care, for this study we just need to send them away to a company called RD Biomed for an extra test called Peptest. This will tell us if fluid from the stomach has travelled into the lungs. Staff at RD Biomed will not see any of your patient's personal information.
2. Secondly, samples from the lungs will be sent to test for any bacteria that would normally occur in the mouth. This would show if material has entered the lung that could cause an infection in the lung. Again, this is a normal test that patients have in the Intensive Care unit, we just need to send extra samples to a laboratory in Cardiff University.

These samples will be stored and shared securely. We will carefully document what samples are taken, when they are taken, how they are stored and when they are transferred to either RD Biomed or Cardiff University for analysis. The samples will be labelled in a way that you cannot be identified from the label. These samples will be destroyed by the end of the study.

As well as extra tests, we collect information on patients in this study (such as if they needed antibiotics). All of this information is gathered from medical notes and medical observations that do not require any additional testing. Only information relevant to comparing the two breathing tubes is collected about your patient.

Importantly, the care the patients receive will be the same whether they have the new tube, the current tube or if they no longer take part in this study.

Here is a schedule of what will happen to your patient:

	Day 0	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	Up to day 28
We will check the patient is eligible to participate in the study	✓								
We ask advice from a friend/relative or doctor that the patient would want to participate in the study	✓								
Patient is randomly assigned to a group to receive either the new breathing tube (PneuX) or the standard tube	✓								
Fluid from above and below the breathing tube is taken and sent to RD Biomed to look for stomach fluid		✓	✓	✓	✓	✓	✓	✓	
Fluid from above and below the breathing tube and sent to Cardiff University to look for bacteria				✓				✓	
Information is gathered about antibiotic use and whether the patient has a chest infection		✓	✓	✓	✓	✓	✓	✓	
Information is gathered from the patient's medical notes about how long they stayed on a ventilator or in hospital.									✓
Once the patient is well enough to decide for themselves we will ask them if they want to stay in the study.		✓	✓	✓	✓	✓	✓	✓	✓

What are the alternatives for treatment if my patient does not participate in the study?

If you decide that your patient would not want to continue to participate in the study they will continue to receive all the usual care that a patient in the Intensive Care Unit would receive.

They will continue to use the breathing tube they already have and this will not be changed. They are both safe and licensed medical devices. We would stop collecting data and sending samples from the point that the patient is taken out of the study and any samples will be destroyed.

What are the possible benefits to taking part in the study?

The purpose of the study is to further medical knowledge and determine what breathing tube would be better for our patients. Results of the study may help future patients, but participation in the study will not directly benefit your patient.

What are the possible risks to taking part in the study?

Risks of taking part in this study are very low. The two breathing tubes in this study are both safety tested and licensed medical devices. The samples that we need for this study are samples that are normally taken as part of routine care and therefore pose no extra risk to your patient.

What happens when the research study stops?

Patients in the research study will have samples collected for the first 7 days of the study. Information taken from medical notes will stop when the patient is discharged from hospital or after 28 days. Whichever happens first.

There is no need for any further follow up for this study. The patient will not need any additional tests or any different care from normal patient care.

Will my patient's participation in the study be kept confidential?

In this research study we will use information from your patient's medical records. We will only use information that we need for the research study. We will let very few people know your patient's name or contact details, and only if they really need it for this study.

Everyone involved in this study will keep your patient's data safe and secure. We will also follow all privacy rules. At the end of the study we will save some of the data in case we need to check it. We will make sure no-one can work out who they are from the reports we write.

Further information is available in Part 2 of this information sheet.

What if there is a problem with the study or I am unhappy about anything to do with the study?

We will keep you informed if there is a problem with the study at any point. If you have any concerns or wish to complain about the way you or your patient has been treated in relation to participating the study, please rest assured these will be dealt with. Further information is available in Part 2 of this information sheet.

Contact details for the Critical Care Research Team:

Dr Matt Wise

Critical Care Consultant

Critical Care Directorate

Critical Care Research Clinical Specialist Nurses

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Part 2

What if relevant new information becomes available?

During the course of this study new information about the treatment being looked at, or the risks and benefits of taking part may come to light. If this were to happen, the Critical Care Research Team would discuss this with you and let you know if this new information may affect your patient.

If any of this information may affect whether your patient stays in the study you will be informed and given as much information as you need to decide if you think your patient should continue to take part or be withdrawn.

We may ask you to sign an updated Nominated Consultee Declaration Form.

Sometimes the research team may decide that the new information means that it is in the best interests of your patient to be withdrawn from the study. If this happens they will explain the reason why to you. This will not affect their ongoing care and treatment.

If the study is stopped for any other reason you will be informed as soon as possible. This will not affect the ongoing care and treatment of your patient.

What will happen if I don't want my patient to continue participating in the study?

You can withdraw your patient from the study at any point. You will not need to provide a reason for withdrawing them if you do not wish to do so. Withdrawal from the study will not affect the ongoing care and treatment that your patient receives in any way.

If you decide to withdraw from the study then we will no longer collect any further information about your patient and any samples will be destroyed. Information collected up to the point of withdrawal may be used in the study.

What if there is a problem?

If you have any concerns regarding the study please speak to Dr Matt Wise, the Critical Care Consultant who is responsible for running the study, or one of the Critical Care Research Clinical Nurse Specialists. Contact details can be found at the end of this information sheet.

Complaints:

If after speaking with the Critical Care Research Team you are still unhappy and wish to make a formal complaint you can do this through the NHS Complaints Procedure.

For complaints and advice please contact the Patient Advice and Liaison Service (PALS) Office on telephone: 029 2074 4095 / 029 2074 3301 or concerns@wales.nhs.uk

Harm:

In the event that something does go wrong and your patient is harmed as a result of participating in the study, there are no special compensation arrangements in place. If your patient is harmed and this is due to somebody's negligence then you or they may have grounds for legal action or a compensation claim against Cardiff and Vale University Health Board. However, you or they may have to pay the legal costs. In this instance the standard NHS complaints procedure is still available.

How will information about your patient be used?

Cardiff and Vale UHB is the organisation sponsoring this study and is based in the United Kingdom.

The sponsor will need to use information from your patient's medical records for this research project.

This information will include their:

- initials,
- NHS number,
- name,
- contact details.

People will use this information to do the research or to check your patient's records to make sure that the research is being done properly.

People who do not need to know who your patient is will not be able to see their name or contact details. Their data will have a code number instead. The sponsor will keep all information about them safe and secure.

Once the study is finished, the sponsor will keep some of the data so they can check the results. They will write reports in a way that no-one can work out that your patient took part in the study.

Cedar (part of Cardiff and Vale University Health Board) is an NHS department responsible for managing this study. NHS researchers in Cedar may see your patient's medical notes for the purposes of ensuring that the study is being carried out correctly. Any information about your patient which leaves the research site will have your name and address removed so that you cannot be identified.

Cardiff and Vale University Health Board will keep identifiable information about your patient for 5 years after the study has finished. This information will be held by Cardiff and Vale University Health Board.

What are your choices about how your information is used?

Your patient can stop being part of the study at any time, without giving a reason, but we will keep information about them that we already have.

We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

You can find out more about how we use your patient's information by contacting the Critical Research Office, as above.

Where can you find out more about how your patient's information is used?

You can find out more about how we use their information:

- at www.hra.nhs.uk/information-about-patients/
- our GDPR generic leaflet available from: https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/data-protection-and-information-governance/gdpr-guidance/templates/template-wording-for-generic-information-document/
- by asking one of the research team by calling 02921 844771 or emailing Judith.White3@wales.nhs.uk
- by sending an email to the Sponsor's data protection officer at: cav.ig.dept@wales.nhs.uk

What will happen to the results of the research study?

When the study has completed, the results will be analysed and published in a peer reviewed medical journal. This will not contain any information which could be used to identify your patient. Further studies may be carried out as a result of this study. Changes in treatments for patients who need a breathing tube may change as a result of any findings of this study.

Who is organising and funding the research?

Cardiff and Vale University Health Board are Sponsoring the study.

The study is funded internally. The PneuX breathing tubes are being given to the hospital free of charge by the manufacturer for this study.

Who has reviewed the study?

Cardiff and Vale University Health Board Research and Development Department have approved the study and a NHS Research Ethics Committee has given a favourable opinion.

Thank you for taking the time to read this information sheet. We appreciate your time and effort.

Contact details for the Critical Care Research Team:

The Chief Investigator for this study is:

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