# Participant 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**

You have been enrolled as a participant in this research project. Because you were too unwell to decide for yourself whether to take part, we took advice about whether you would want to take part from either a friend or a relative of yours (a personal consultee) or a doctor who is not involved in this study (nominated consultee). 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 you before going ahead with these treatments. Your serious condition meant that you were too unwell to decide whether you wanted 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.

We are asking you whether you want to continue to take part in this study. 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. Feel free to discuss it with friends, relatives, and any other doctors if you wish. 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 have I been chosen to participate in the study?**

You were chosen because you needed breathing support in the Intensive Care Unit to help you through your current illness and matched the list of requirements which made you right for our study.

**Do I have to continue to take part in the study?**

Your involvement in the study is completely voluntary.

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 wish to continue to take part in the study we will ask you to sign a **Participant Consent Form**. If you change your mind at any point and do not want to continue taking part in the study anymore, you can withdraw from the study.

If you decide to not take part in the study, we will stop collecting any more information about your medical care. We will use information already gathered up to the point that you leave the study. It will not affect the standard of care that you receive in any way.

**What will happen to me if I continue to participate in the study?**

You have already received the treatment involved in this study. When your breathing was supported you had one of the tested breathing tubes to help you breath. It was a 50/50 chance of having either the new tested breathing tube (the PneuX) or the current breathing tube (the Taperguard).

Whilst your breathing was supported we sent some samples for extra testing. These samples were collected via routine methods that we use on our patients.

Two samples have been taken as follows:

1. Firstly, a sample of fluid was 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 Unit, for this study we just needed 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 travelled into the lungs. Staff at RD Biomed will not see any patient's personal information.
2. Secondly, samples from the lungs were 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 were stored and shared securely. We carefully documented what samples were taken, when they were taken, how they were stored and when they were transferred to either RD Biomed or Cardiff University for analysis. The samples will be labelled in a way that you could not be identified from the label. These samples will be destroyed by the end of the study.

As well as extra tests, we have collected information on patients in this study (such as if you 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 was collected about you.

Importantly, the care you received was the same whether you had the new tube, the current tube or if you no longer wish to take part in this study.

By continuing in the study, we will continue to collect data from your medical records until you are discharged or up to 28 days since your participation in this study. Whichever occurs sooner. The data collected will only be relevant to this study. For example, we are interested to see if antibiotics are needed more with either tube. This is the sort of information we will access.

There is no need for long term follow up or further appointments.

Here is a summary of what has happened/will happen to you:

| | Day 0 | Day 1 | Day 2 | Day 3 | Day 4 | Day 5 | Day 6 | Day 7 | Up to day 28 |
|---|---|---|---|---|---|---|---|---|---|
| We will check that you are eligible to participate in the study | ✓ | | | | | | | | |
| We ask advice from a friend/relative or doctor that you would want to participate in the study | ✓ | | | | | | | | |
| You are 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 you have a chest infection | | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | |
| Information is gathered you're your medical notes about how long you stayed on a ventilator or in hospital. | | | | | | | | | ✓ |
| Once you are well enough to decide for yourself we will ask you if you want to stay in the study. | | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ |

**What are the alternatives for treatment if I do not participate in the study?**

You have received all the usual treatment for intensive care patients. The only difference in your care was the breathing tube we used. If you do not wish to continue to participate in this study, we will no longer collect data regarding the remainder of your admission in hospital. We will use the collected data up to the point that you have left the study. If you choose not to take part we will destroy any samples taken for the study.

**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 you.

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

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

**What happens when the research study stops?**

There is no need for any further follow up for this study. You will not need any additional tests or any different care from normal patient care. Information taken from medical notes will stop when you are discharged from hospital or after 28 days. Which ever happens first.

**Will my participation in the study be kept confidential?**

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

Everyone involved in this study will keep your 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 you 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 have 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
University Hospital of Wales
Heath Park

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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 you.

We may ask you to sign an updated Participant Consent Form.

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

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

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

If you decide to withdraw from the study then we will no longer collect any further information about you 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 you are harmed as a result of participating in the study, there are no special compensation arrangements in place. If you are 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 you 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 medical records for this research project.

This information will include your:

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

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

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead. The sponsor will keep all information about you 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 you 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 medical notes for the purposes of ensuring that the study is being carried out correctly. Any information about you 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 you 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?**

You can stop being part of the study at any time, without giving a reason, but we will keep information about you 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 information by contacting the Critical Research Office, as above.

**Where can you find out more about how my information is used?**

You can find out more about how we use your 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 you. 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 an NHS Research Ethics Committee has given a favourable opinion.

Thank you for taking the time to read this information sheet during a very stressful time. 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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