

Participant Information Sheet

The Inflate Study; An Imaging Study of the Soft Palate in the Upper Airway

Sponsor:	Fisher & Paykel Healthcare Ltd
Co-ordinating Investigator:	Assoc. Prof. Alys Clark
Sub Investigator:	Mr Jamie Miller
Study Site:	Auckland Bioengineering Institute, University of Auckland
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Ethics committee ref.:	HDEC 21455

You are invited to take part in a study to further understand the soft palate's place in the upper airway with magnetic resonance imaging (MRI). Whether or not you take part is your choice. If you don't want to take part, you don't have to give a reason. If you do want to take part now, but change your mind later, you can pull out of the study at any time.

This Participant Information Sheet will help you decide if you'd like to take part. It sets out why we are doing the study, what your participation will involve, the benefits and risks of your participation, and what happens after the study ends. We will go through this information with you and answer any questions you may have.

You do not have to decide today whether or not you will participate in this study. Before you decide you may want to talk about the study with other people, such as family, whānau, friends, or healthcare providers. Feel free to do this.

If you agree to take part in this study, you will be asked to sign the Consent Form on the last page of this document. You will be given a copy of the Participant Information Sheet and the Consent Form to keep.

This document is 11 pages long, including the Consent Form. Please make sure you have read and understood all the pages.

VOLUNTARY PARTICIPATION AND WITHDRAWAL FROM THIS STUDY

Participation in this study is entirely voluntary. This means it is up to you whether you want to be involved or not. If you choose to participate, you are free to change your mind and withdraw from the study at any time that works for you, without any negative consequences. You do not have to give a reason for withdrawal and you may withdraw even after you have started your participation.

WHAT IS THE PURPOSE OF THE STUDY?

The soft palate is a group of muscles that sits at the back of the mouth in the upper airway. It plays an important role in breathing, swallowing and speech. This study is being conducted to understand and define how the shape and position of the soft palate may impact the flow of air through the upper airway as we breathe. We aim to study the soft palate under conditions with limited attention in

previous research, utilising magnetic resonance imaging (MRI) and measures of upper airway resistance. This includes different body positions and the addition of positive airway pressure therapy, known as non-invasive ventilation (NIV).

This information will not only help to further understand this important piece of human anatomy for clinical decision-makers but may also contribute to the development of products for use with NIV therapy.

HOW IS THE STUDY DESIGNED?

This study is expected to include up to 50 participants recruited from the local Auckland region. If you agree to participate, you will attend a single visit at an imaging facility of the Auckland Radiology Group for up to 2 hours. Your visit will be arranged by a member of the research team either by phone or email, whichever is most convenient for you. You will also get a reminder email 24h prior to your study visit.

This study will involve the following procedures that are also explained in further detail below:

- **Magnetic Resonance Imaging (MRI):** A safe imaging procedure that will allow us to take images of your upper airway without the use of ionising radiation (e.g. X-ray). MRI requires you to lie still inside a scanner, a relatively confined space, with some equipment that will be placed around your head and neck, known as a coil. This may cause some feeling of claustrophobia and you can take breaks from lying inside the scanner as you feel necessary.
- **Non-invasive ventilation (NIV):** A form of positive airway pressure therapy usually prescribed to patients with trouble breathing. This may be in a hospital or chronically at home. The positive pressure is provided by a device called a ventilator and is connected to you with plastic tubing and a mask you wear on your face. We will use NIV inside the MRI scanner to understand how this therapy impacts the shape and size of the soft palate and the resulting airflow associated with breathing.
- **Upper Airway Resistance Measurements:** Upper Airway Resistance is a term used to describe how hard or easy it is to breathe. It is a measure of how the structures of the upper airway impact the flow of air as we breathe. To determine upper airway resistance, we will use an assessment called rhinomanometry. This involves wearing a specific mask on your face that helps us measure the pressure and airflow as you breathe normally. Doctors use rhinomanometry to help understand if anything is blocking your upper airway, such as congestion, allergies, or other upper airway obstruction. We will also use a technique called acoustic rhinometry, which utilises a special microphone that is held under your nose and measures the internal area of the upper airway with sound waves.

The research team will explain each procedure to you before completing each assessment and you are encouraged to ask questions at any point during the study.

WHO CAN TAKE PART IN THE STUDY?

You have been invited to take part in this study as you are over the age of 18, you are not claustrophobic, you do not have any implants, such as a pacemaker, you have no history of respiratory disease, you have had no symptoms of cold or flu in the last 3 days you are not pregnant and you are able to give informed consent.

WHAT WILL MY PARTICIPATION IN THE STUDY INVOLVE?

After reviewing this information sheet, you will be contacted by a member of the research team, who will be available to answer any questions you might have about the study. If you agree to participate, an appointment time for your first study visit will be booked.

The study will involve a single 2-hour visit to an Auckland Radiology Group (ARG) facility in Auckland City. It is recommended you wear comfortable clothes for your visit. You will spend up to 1½ hours in an MRI scanner, including breaks.

Consent: Upon arrival at the imaging facility, a team member will take you through all procedures that you will participate in during your visit. There will be time to ask any additional questions about your visit. If you haven't already you will be asked to read and sign the Informed Consent Form. Completing this form confirms that you are aware of and understand the benefits and risks of participating in this study. You will also be asked to provide your name and IRD number for a tax form relating to your reimbursement.

MRI: MRI requires you not to have any metal on your person. Safe storage for your belongings will be available. ARG staff will require you to sign their safety sheet. You may be asked to give your name, date of birth and weight to the imaging staff, however this will not be linked to your study. You may take breaks between MRI scans. The MRI scanner requires a coil to be placed over your head and neck (Figure 1A). You will be asked to lie in different positions inside the scanner while images are acquired. Images will be acquired over 5 seconds up to 8 minutes at a time. You will have earplugs and headphones to wear while inside the scanner. We may issue some instructions to you through the headphones while you are inside the scanner, such as "Please breathe through your mouth". Any breathing patterns we may instruct you to do will be practised outside the MRI scanner. You will also use an NIV device during the MRI scanning. We will again ask you to breathe in specific patterns while using the ventilator. There will be a button you can press that allows you to have a break from scanning at any time. The procedure requires you to be still during the image acquisition (up to 8 minutes), research staff will communicate when you need to be still and when you can relax. You may stop and exit the MRI scanner whenever you need to.

NIV: During your visit you will spend a short amount of time on NIV therapy, as mentioned, both inside and outside of the MRI scanner. Prior to using NIV inside the MRI scanner, you will experience the therapy outside of the scanner. The research team will ensure the mask fits you comfortably, and that you can breathe easily (Figure 1B). During this time, you will practice some of the breathing patterns that we aim to see inside the MRI scanner, such as mouth breathing. This initial set-up on NIV will last approximately 5-10 minutes. You may be asked to breathe different to your normal breathing pattern. This may cause some temporary light headedness. You can stop at any time you wish to.

Upper airway resistance: During your study visit, your upper airway resistance will be measured with a procedure called rhinomanometry including acoustic rhinometry. These are both easy, non-invasive measures that require you to breathe normally in and out of your nose or mouth. During rhinomanometry you will be wearing a specific mask with a small straw piece placed on your lips (Figure 1C). Acoustic rhinometry involves having a special microphone placed underneath your nose (Figure 1D). These tests will take approximately 15-20 minutes to complete.



A



B



C



D

Figure 1. (A) an MRI scanner commonly found at ARG locations, with a “coil” placed over the head and neck. (B) An example of an NIV mask that you will wear with NIV. (C) The Rhinomanometry procedure, with a specific mask held to the face. (D) Acoustic rhinometry, with a special microphone held under the nose.

WHAT ARE THE POSSIBLE RISKS OF THIS STUDY?

All procedures conducted during this study are safe. However, there is a risk that you may experience some side effects during your participation in this study.

- You may experience some temporary light-headedness due to the NIV therapy and an increased rate of breathing.
- You may experience some temporary discomfort around your nostril during the rhinomanometry due to the soft foam insert.
- The MRI scanner is a confined space with loud noises when in operation. You may experience discomfort and claustrophobia when you are in the scanner.

Members of the research team will be available to support you throughout your visit, and you can take a break or withdraw from the study at any point without any negative consequences.

WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY?

You will likely receive no direct benefit from participating in this study. However, the knowledge gained during this study may provide future clinical benefits to patients who require respiratory support.

WILL ANY COSTS BE REIMBURSED?

You, as a participant, will not have to pay anything to be part of this study. The research is being funded by the sponsor of the study, Fisher and Paykel Healthcare.

As a participant in this study, travel will be provided to the imaging facility via taxi or uber and you will be reimbursed \$100 NZD (net of tax) for your time. If you withdraw from the study after arriving at the site, your time will be reimbursed *pro rata*.

Fisher and Paykel Healthcare will cover the tax cost of this payment. Participants will be required to provide their IRD numbers and fill out an IR330C form. Fisher and Paykel Healthcare are required to keep this form for at least 7 years, after which it will be deleted from file.

WHAT IF SOMETHING GOES WRONG?

“Commercially sponsored” studies:

As Fisher and Paykel Healthcare fund this research study, if you are injured as a result of your participation, you **won't** be eligible for compensation from ACC.

However, Fisher and Paykel Healthcare has satisfied the Health and Disability Ethics Committee that approved this study that it has up-to-date insurance for providing participants with compensation if they are injured as a result of taking part in this study.

New Zealand ethical standards require compensation for injury to be at least ACC equivalent. Compensation should be appropriate to the nature, severity and persistence of your injury and should be no less than would be awarded for similar injuries by New Zealand's ACC scheme.

The insurance policy is consistent with the Standard Indemnity and Compensation Agreement (sICA) for Clinical Trials in New Zealand Public Health Organisations

An initial decision whether to compensate you would be made the by the sponsor and/or its insurers.

If they decide not to compensate you, you may be able to take action through the Courts for compensation, but it could be expensive and lengthy, and you might require legal representation. You would need to be able to show that your injury was caused by participation in the trial.

You are strongly advised to read the Industry Guidelines and ask questions if you are unsure about what they mean for you.

If you have private health or life insurance, you may wish to check with your insurer that taking part in this study won't affect your cover.

WHAT WILL HAPPEN TO MY INFORMATION?

During this study the research team will record information about you and your data. This includes the results of measurements recorded taken during your visit (i.e. upper airway resistance) and the medical imaging data of your upper airway including your head and neck. You cannot take part in this study if you do not consent to the collection of this information.

The data collected will be stored as either 'Identifiable Information' or 'De-identified Information':

Identifiable Information

Identifiable information is any data that could identify you (e.g. your name, date of birth, or address). The research team will have access to your identifiable information that is collected for the purposes of the study.

Staff from the imaging vendor may record your identifiable data, such as your name, date of birth and/or weight as part of their normal safety protocols, to process and/or report your imaging data. This information is not shared with the research team but will be kept in their secure patient

management system as per best practice, this is held in perpetuity and won't be shared to researchers outside the scope of this study.

Fisher and Paykel Healthcare are required to retain your IR330C form on file for at least 7 years. This form will contain your full name and IRD number. This information is not attached to your study data and is only used to pay tax on participation reimbursement payments. After the minimum filing period, your form will be deleted from file.

Rarely, it may be necessary to share your information with other people – for example, if there is a serious threat to public health or safety, or to the life or health of you or another person or if the information is required in certain legal situations.

De-identified (Coded) Information

To make sure your personal information is kept confidential, information that identifies you will not be included in any report generated by the research team, or any study data sent to the sponsor. Instead, you will be identified by a code. The research team at the study site will keep a list linking your code with your name, so that you can be identified by your coded data if needed. The results of the study may be published or presented, but not in a form that would reasonably be expected to identify you.

Anonymised Information

The sponsor may remove the code from your de-identified information – this is called 'anonymisation'. This makes it very difficult (but not impossible) to identify the information that belongs to you.

Future Research Using Your Information

If you agree, your anonymised data, such as imaging and upper airway resistance data, may be used for future research related to upper airway anatomy. This anonymised data may also be used for other medical and/or scientific research that is unrelated to the current study. You will not be told when future research is undertaken using your anonymised information. You will not get reports or other information about any future research that is done using your anonymised information.

Your information may be used indefinitely for future research unless you withdraw your consent. However, it may be extremely difficult or impossible to access your information, or withdraw consent for its use, once your anonymised information has been shared for future research.

Security and Storage of Your Information

Your identifiable information is held with University of Auckland during the study on secure electronic servers. After the study it is transferred to a secure archiving site and stored for at least 10 years, then destroyed. Your de-identified information will be entered into electronic case report forms and sent through a secure server to the sponsor. De-identified study information will be kept by the sponsor in secure, cloud-based storage indefinitely. All storage will comply with local and international data security guidelines.

Risks

Although efforts will be made to protect your privacy, absolute confidentiality of your information cannot be guaranteed. Even with coded and anonymised information, there is no guarantee that you cannot be identified. The risk of people accessing and misusing your information (e.g. making it harder for you to get or keep a job or health insurance) is currently very small but may increase in the future as people find new ways of tracing information.

This research includes basic information such as your ethnic group, age range, BMI and sex. It is possible that this research could one day help people in the same groups as you. However, it is also

possible that research findings could be used inappropriately to support negative stereotypes, stigmatize, or discriminate against members of the same groups as you.

We will scan images of your upper airway that unavoidably include your face. Due to the nature of facial recognition software, this information could potentially be used to identify you. However, this risk is mitigated by all imaging data remaining on a secure electronic server at the University of Auckland with password-controlled access. This means the risk is low, however we cannot guarantee that it will not happen.

Rights to Access Your Information

You have the right to request access to your information held by the research team. You also have the right to request that any information you disagree with be corrected.

Please ask if you would like to access the results of your information during the study.

If you have any questions about the collection and use of information about you, you should ask any research staff.

Ownership Rights

Information from this study may be used in the development of a commercial product. The rights to these potential future products will belong to Fisher and Paykel Healthcare. You and your family will not receive any financial benefits or compensation, nor have any rights in any developments, inventions, or other discoveries that might come from this information.

Māori Data Sovereignty

Māori data sovereignty is about protecting information or knowledge that is about (or comes from) Māori people. We recognise the taonga of the data collected for this study. To help protect this taonga:

- We have consulted with Mr Hendon Stephens about the collection, ownership, and use of study data.
- We allow Māori organisations to access de-identified study data, for uses that may benefit Māori.
- The research team will conduct ongoing consultation and focus group discussions with Māori and Pacifica peoples in collaboration with Iwi United Engagement (IUE) and Moana Connect. You are welcome to discuss this with the research team.

WHAT HAPPENS AFTER THE STUDY OR IF I CHANGE MY MIND?

Participation in the study is completely up to you. If you change your mind and decide to withdraw from the study, you can do so at any time without penalty or loss of benefits to which you are otherwise entitled. You will be reimbursed for your travel expenses fully and your time spent participating will be reimbursed *pro rata*. If you want to withdraw from the study, please contact a member of the research team (ph. 027 303 2944, or further contact details below).

If you agree, information collected up until your withdrawal from the study will continue to be used and included in the study. You may ask for it to be deleted when you withdraw, unless you withdraw after the study analyses have been undertaken.

CAN I FIND OUT THE RESULTS OF THE STUDY?

A description of this trial will be available on the clinical trials registry website (<https://www.clinicaltrials.gov/>). This website will not include information that can identify you. At most, it will include a summary of study results.

In the future the results of the study may be published as presentations and/or journal articles. Any publication would not be in a form where you could be identified.

If you would like a plain English summary of the study results, please ask a team member, they will advise you on when this will be available. You may also ask for your individual study data at any time during the study, however, the Auckland Radiology Group are unable to provide your individual images from this study nor will the imaging become part of your health record.

In the case of incidental or abnormal findings, you will consent to having these reported to your GP and you will need to provide the contact details for this.

WHO IS FUNDING THE STUDY?

Fisher and Paykel Healthcare are funding this study.

The Co-ordinating Investigator, Alys Clark, is an independent investigator with the University of Auckland, Auckland Bioengineering Institute.

The sub-investigator, Jamie Miller, is an employee of Fisher and Paykel Healthcare and a doctoral candidate with The University of Auckland, Auckland Bioengineering Institute

WHO HAS APPROVED THE STUDY?

This study has been approved by an independent group of people called a Health and Disability Ethics Committee (HDEC), who check that studies meet established ethical standards. The Northern B Health and Disability Ethics Committee has approved this study.

WHO DO I CONTACT FOR MORE INFORMATION OR IF I HAVE CONCERNS?

If you have any questions, concerns, or complaints about the study at any stage, you can contact:

Name (position): Alys Clark (Co-ordinating Investigator)
Telephone number: 09 373 7599 Ext: 85604
Email: alys.clark@auckland.ac.nz

Name (position): Jamie Miller, (Sub Investigator)
Telephone number: 027 303 2944
Email: jamie.miller@auckland.ac.nz

If you want to talk to someone who isn't involved with the study, you can contact an independent health and disability advocate on:

Phone: 0800 555 050
Fax: 0800 2 SUPPORT (0800 2787 7678)
Email: advocacy@advocacy.org.nz
Website: <https://www.advocacy.org.nz/>

For Māori cultural support please contact:

Name (position): Hendon Stephens, Cultural Advisor, AUT
Telephone number: 021 131 6231
Email: hendon.stephens@aut.ac.nz

You can also contact the health and disability ethics committee (HDEC) that approved this study on:

Email: hdecs@health.govt.nz
Phone: 0800 400 569 (Ministry of Health general enquiries)
Study Reference: HDEC reference number 21455

Consent Form

An Imaging Study of the Soft Palate in the Upper Airway

Please tick to indicate your consent to the following

I have read the Participant Information Sheet, and I fully comprehend what it says.	Yes <input type="checkbox"/>
I have been given sufficient time to consider whether or not to participate in this study.	Yes <input type="checkbox"/>
I have had the opportunity to use a legal representative, whanau/ family support, a friend, a cultural advisor or a healthcare provider to help me ask questions and understand the study.	Yes <input type="checkbox"/>
I am satisfied with the answers I have been given regarding the study, and I have a copy of this consent form and information sheet.	Yes <input type="checkbox"/>
I understand that taking part in this study is voluntary (my choice) and that I may withdraw from the study at any time without needing reason and without negative consequences to myself.	Yes <input type="checkbox"/>
I consent to the research team collecting and processing my information.	Yes <input type="checkbox"/>
I understand that my participation in this study is confidential and that no material, which could identify me personally, will be used in any reports on this study.	Yes <input type="checkbox"/>
I understand the compensation provisions in case of injury during the study.	Yes <input type="checkbox"/>
I know who to contact if I have any questions about the study in general.	Yes <input type="checkbox"/>
I understand my responsibilities as a study participant.	Yes <input type="checkbox"/>
I consent to my GP or current provider being informed of any significant abnormal results obtained during the study.	Yes <input type="checkbox"/>
I agree to an approved auditor appointed by the New Zealand Health and Disability Ethics Committees, or any relevant regulatory authority, or their approved representative, reviewing my relevant medical records for the sole purpose of checking the accuracy of the information recorded for the study.	Yes <input type="checkbox"/>
If I decide to withdraw from the study, I agree that the information collected about me up to the point when I withdraw may continue to be processed.	Yes <input type="checkbox"/> No <input type="checkbox"/>
I consent to my anonymised data being used in future medical or scientific research that may be unrelated to the current study.	Yes <input type="checkbox"/> No <input type="checkbox"/>
I consent to being contacted by the research team to participate in future studies related to the current study.	Yes <input type="checkbox"/> No <input type="checkbox"/>
I wish to receive a summary of the results of the study.	Yes <input type="checkbox"/> No <input type="checkbox"/>

Declaration by participant:

I hereby consent to take part in this study.

Participant's name: _____

Signature: _____

Date: _____

Optional contact details for future communication (Ph. or E-mail): _____

Declaration by member of research team:

I have given a verbal explanation of the research project to the participant, and have answered the participant's questions about it.

I believe that the participant understands the study and has given informed consent to participate.

Researcher's name: _____

Signature: _____

Date: _____