

**Participant Information Sheet - Patients**

Victorian Heart Hospital

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| **Title** | Effect of physical counter pressure manoeuvres on the incidence of Vasovagal Response to Venous Cannulation  **Cannulation** *roject Title]* | |
| **Principle Investigators** | Mrs Rebecca Woodley | |
| **Associate Investigator** | Mrs Sujie Martin, Dr Sean Tan | |
| **Location** | Victorian Heart Hospital, 631 Blackburn Road, Clayton, Victoria 3168. | |
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**Part 1 What does my participation involve?**

**1 Introduction**

You are invited to take part in this research study because you have been referred by your doctor to attend our department for a CT coronary angiogram (CTCA). You will need to have intravenous cannulation, also known as an intravenous drip, for this scan. A small number of patients may experience a vasovagal response or vasovagal syncope, which is a sensation of light-headedness, nausea or fainting, during intravenous cannulation.

This research project is testing preventative strategies for vasovagal responses induced by intravenous cannulation that is performed for your scan. The strategies involve counter pressure manoeuvres (CPM), which include hand gripping and/or adopting a lying down position during intravenous cannulation.

This Participant Information Sheet/Consent Form tells you about the research project. It explains the tests and treatments involved. Knowing what is involved will help you decide if you want to take part in the research.

Please read this information carefully. Ask questions about anything that you don’t understand or want to know more about. Before deciding whether or not to take part, you might want to talk about it with a relative, friend or your local doctor.

Participation in this research is voluntary. If you don’t wish to take part, you don’t have to. You will receive the best possible care whether or not you take part.

If you decide you want to take part in the research project, you will be asked to sign the consent section. By signing it you are telling us that you:

• Understand what you have read

• Consent to take part in the research project

• Consent to have the tests and treatments that are described

• Consent to the use of your personal and health information as described.

You will be given a copy of this Participant Information and Consent Form to keep.

**2 What is the purpose of this research?**

There is currently limited information on techniques that could be used to reduce the risk of vasovagal response in patients undergoing intravenous cannulation.

There are three aims of this research study:

1. To describe the proportion of patients who have vasovagal responses during intravenous cannulation
2. To identify predisposing factors to the development of vasovagal response in patients who undergo intravenous cannulation
3. To investigate if CPM (hand gripping and posture) can reduce the rate and duration of vasovagal responses.

**3 What does participation in this research involve?**

If you agree to take part and sign the consent form, you will be included in the study. Participation in this study is voluntary. It is completely up to you whether or not you participate, you can withdraw from the study at any time. If you decide not to participate, it will not affect the treatment you receive now or in the future.

This is a randomised controlled research project, as for now we do not know which treatment is best for preventing and treating vasovagal syncope. To find out we need to compare different treatments. Participants who consent to enter the study will be screened for eligibility first and subsequently assigned into one of the four groups if they are eligible:

1. Standard care with no interventions (normal practice with intravenous cannulation in a sitting up position)
2. Adopting a lying down position during cannulation
3. Hand grip exercise with a stress ball during cannulation
4. Adopting a lying down position and hand grip exercises with a stress ball during cannulation

The results between the four groups will be compared to see if one is better. To try to make sure the groups are the same, each participant is put into a group by chance (random).

Participants will be given instructions and educations regarding correct CPM techniques before intravenous cannulation by their treating nurses. The process would normally take about 10 to 15 minutes, and participant’s symptoms, heart rates, and blood pressures will be continuously monitored and recorded during the procedure.

There is no follow up required after the procedure. Data collected from this study will be de-identified and stored in a place accessible to the study investigators only. In any publication, information will be provided in such a way that you cannot be identified. Results of the study will be provided to your email or home address if requested.

This research project has been designed to make sure the researchers interpret the results in a fair and appropriate way and avoids study participants jumping to conclusions. There are no additional costs associated with participating in this research project, nor will you be paid. All medication, tests and medical care required as part of the research project will be provided to you free of charge.

**4 What do I have to do?**

In preparation for the CTCA, you will have been provided with these standardised instructions when you were informed of your scan date and time:

* Please **DO NOT take any caffeine** (tea, coffee, cola, chocolate, milo, sports drinks or energy drinks) for **24 hours before your scan**.
* **DO NOT** smoke or drink alcohol for 12 hours before your scan.
* **DO NOT EAT** solid food for **2 hours before the scan**, however you may continue to drink water
* Please take ALL medications as normal

You will need to be able to tolerate a lying down position and have normal strength of upper extremities to participate in this study.

**5 Do I have to take part in this research project?**

Participation in any research project is voluntary. If you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage.

If you do decide to take part, you will be given this Participant Information and Consent Form to sign and you will be given a copy to keep.

Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your routine treatment, your relationship with those treating you or your relationship with Victorian Heart Hospital.

**6 What are the possible benefits of taking part?**

We cannot guarantee or promise that you will receive any benefits from this research; however, this study can help us better understand precipitating factors and treatment strategies of vasovagal syncope. The information learnt from this study will help guide how we can prevent vasovagal responses in future patients having intravenous cannulation for CTCA.

**7 What are the possible risks and disadvantages of taking part?**

There are no risks involved in being in this study. As you are attending the hospital for a CTCA, you will still have a cannula inserted for contrast administration to facilitate the scan regardless of whether you participate in the study or not. Participation in the study may only include changes in posture and hand gripping exercise during cannula insertion.

**8 Alternative treatment**

No treatment is being withheld to anyone entering the study. Choosing not to participate in the study will not in any way affect the level of care you receive or the CTCA you are about to have.

**9 What if I withdraw from this research project?**

If you decide to withdraw from the project, please notify a member of the research team before you withdraw. This notice will allow that person or the research supervisor to discuss any health risks or special requirements linked to withdrawing.

If you do withdraw your consent during the research project, the study doctor and relevant study staff will not collect additional personal information from you, although personal information already collected will be retained to ensure that the results of the research project can be measured properly and to comply with law. You should be aware that data collected by the sponsor up to the time you withdraw will form part of the research project results. If you do not want them to do this, you must tell them before you join the research project

**10 Could this research project be stopped unexpectedly?**

If the study is ceased unexpectedly, you will be informed via email that the research project has ceased and the reason for early cessation. Your data (de-identified) will be stored within an encrypted database for a period of 7 years, then disposed in an unidentified secure manner.

This research project may be stopped unexpectedly for a variety of reasons. These may include reasons such as:

• Unacceptable side effects

• The treatment being shown not to be effective

• The treatment being shown to work and not need further testing

**11 What happens when the research project ends?**

If you give us your permission by signing the consent document, we plan to publish the results. In any publication, information will be provided in such a way that you cannot be identified. Results of the study will be provided to your email or home address if requested.

**Part 2 How is the research project being conducted?**

**12 What will happen to information about me?**

By signing the consent form you consent to the study doctor and relevant research staff collecting and using personal information about you for the research project. Any information obtained in connection with this research project that can identify you will remain confidential. Your information will only be used for the purpose of this research project and it will only be disclosed with your permission, except as required by law.

Information about you may be obtained from your health records held at this and other health services for the purpose of this research. By signing the consent form you agree to the study team accessing health records if they are relevant to your participation in this research project.

It is anticipated that the results of this research project will be published and/or presented in a variety of forums. In any publication and/or presentation, information will be provided in such a way that you cannot be identified, except with your permission.

In accordance with relevant Australian and Victorian privacy and other relevant laws, you have the right to request access to your information collected and stored by the research team. You

also have the right to request that any information with which you disagree be corrected. Please

contact the study team member named at the end of this document if you would like to access your information.

During the study, a unique study number will be used to identify you. For the purposes of this study, we will collect your age, sex and relevant medical history. Your name and any other personal information will not be collected. It will not be possible to individually identify you in any publication or presentation resulting from this study. The information collected about you in this study will be kept in a secure place for at least 7 years, and may be used for future research projects that will be reviewed and approved by an ethics committee and then disposed of in an unidentified manner.

Any information obtained for the purpose of this research project that can identify you will be treated as confidential and securely stored. It will be disclosed only with your permission, or as required by law.

**13 Complaints and compensation**

This study will only involve adopting a lying position and/or hand grip exercises with a stress ball at time of intravenous cannulation. Hence, we do not foresee any injury resulting from participation in this study.

However, if you suffer any injuries or complications as a result of this research project, you should contact the study team as soon as possible and you will be assisted with arranging appropriate medical treatment. If you are eligible for Medicare, you can receive any medical treatment required to treat the injury or complication, free of charge, as a public patient in any Australian public hospital.

**14 Who has reviewed the research project?**

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this research project have been approved by the HREC of Monash Health.

This project will be carried out according to the *National Statement on Ethical Conduct in Human Research (2018)*. This statement has been developed to protect the interests of people who agree to participate in human research studies.

**15 Further information and who to contact**

If you want any further information concerning this project or if you have any medical problems which may be related to your involvement in the project (for example, any side effects), you can contact the principal study investigator Rebecca Woodley on 03 9511 2230 or Sujie Martin on 03 9511 2231**.**

**Clinical contact persons**

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| Name | Rebecca Woodley |
| Position | Nurse Unit Manager |
| Telephone | (03) 9511 2230 |
| Email | Rebecca.Woodley@monashhealth.org |

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| --- | --- |
| Name | Sujie Martin |
| Position | Associate Nurse Unit Manager |
| Telephone | (03) 9511 2231 |
| Email | Sujie.Martin@monashhealth.org |

For matters relating to research at the site at which you are participating, the details of the local site complaints person are:

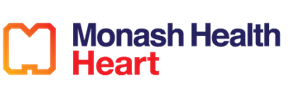
**Complaints contact person**

|  |  |
| --- | --- |
| Name | HREC Executive Officer |
| Position | HREC Executive Officer |
| Telephone | (03) 9594 4611 |
| Email | research@monashhealth.org |

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then you may contact:

**Reviewing HREC approving this research** **and HREC Executive Officer details**

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| --- | --- |
| Reviewing HREC name | Monash Health Human Research Ethics Committee |
| HREC Executive Officer | HREC Executive Officer |
| Telephone | (03) 9594 4611 |
| Email | research@monashhealth.org |



**Consent Form -** *Adult providing own consent*

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| --- | --- |
| **Title** | Effect of physical counter pressure manoeuvres on the incidence of Vasovagal Response to Venous Cannulation  **Cannulation** *roject Title]* |
| **Principle Investigators** | Mrs Rebecca Woodley & Mrs Sujie Martin |
| **Associate Investigator** | Dr Sean Tan |
| **Location** | Victorian Heart Hospital, 631 Blackburn Road, Clayton, Victoria 3168. |

**Declaration by Participant**

I have read the Participant Information Sheet or someone has read it to me in a language that I understand.

I understand the purposes, procedures and risks of the research described in the project.

I give permission for my doctors, other health professionals, hospitals or laboratories outside this hospital to release information to Victorian Heart Hospitalconcerning my disease and treatment for the purposes of this project. I understand that such information will remain confidential.

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I freely agree to participate in this research project as described and understand that I am free to withdraw at any time during the study without affecting my future health care.

I understand that I will be given a signed copy of this document to keep.

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|  | Name of Participant (please print) | |  |  |  |  |
|  | | | | | | |
|  | Signature |  | | Date |  |  |
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|  | Name of Witness\* to Participant’s Signature (please print) | |  | | |  |
|  | | | | | | |
|  | Signature |  | | Date |  |  |
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\* *Witness is not to be the investigator, a member of the study team or their delegate. In the event that an interpreter is used, the interpreter may not act as a witness to the consent process. Witness must be 18 years or older.*

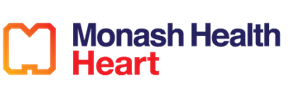
**Declaration by Study Doctor/Senior Researcher†**

I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation.

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|  | Name of Study Doctor/  Senior Researcher† (please print) | |  | | |  |
|  | | | | | |  |
|  | Signature |  | | Date |  |  |
|  | | | | | | |

† A senior member of the research team must provide the explanation of, and information concerning, the research project.

Note: All parties signing the consent section must date their own signature.



**Form for Withdrawal of Participation -** *Adult providing own consent*

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| --- | --- |
| **Title** | Effect of physical counter pressure manoeuvres on the incidence of Vasovagal Response to Venous Cannulation  **Cannulation** *roject Title]* |
| **Principle Investigators** | Mrs Rebecca Woodley |
| **Associate Investigator** | Mrs Sujie Martin, Dr Sean Tan |
| **Location** | Victorian Heart Hospital, 631 Blackburn Road, Clayton, Victoria 3168. |

**Declaration by Participant**

I wish to withdraw from participation in the above research project and understand that such withdrawal will not affect my routine treatment, my relationship with those treating me or my relationship with Victorian Heart Hospital.

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|  | | | | | | |
|  | Name of Participant (please print) | |  |  |  |  |
|  | | | | | | |
|  | Signature |  | | Date |  |  |
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**Declaration by Study Doctor/Senior Researcher†**

I have given a verbal explanation of the implications of withdrawal from the research project and I believe that the participant has understood that explanation.

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|  | Name of Study Doctor/  Senior Researcher† (please print) | |  | | |  |
|  | | | | | |  |
|  | Signature |  | | Date |  |  |
|  | | | | | | |

† A senior member of the research team must provide the explanation of and information concerning withdrawal from the research project.

Note: All parties signing the consent section must date their own signature.