A RANDOMISED CONTROLLED TRIAL ASSESSING WHETHER PRIMING INTRAVENOUS ADMINISTRATION SETS WITH MONOCLONAL ANTIBODIES WILL REDUCE CHAIR TIME IN THE OUTPATIENT SETTING

THE PRIMING PRACTICE STUDY

PARTICIPANT INFORMATION AND CONSENT

THE ROYAL BRISBANE AND WOMENS HOSPITAL

Investigators & affiliations

Principal Investigators,

Francesca Boyte	Registered Nurse, Oncology Day Therapy Unit
Dr Nicole Gavin	Nurse Researcher, Cancer Care Services & Queensland University of Technology

Associate investigators/collaborators,

Michael Smith	Nursing Director, Cancer Care Services
Therese Hayes	Nurse Unit Manager, Oncology Day Therapy Unit & Oncology Procedure Unit
Marianne Fenton	Associate Nurse Unit Manager, Oncology Day Therapy Unit & Oncology Procedure Unit
Grant Partridge	Pharmacist, Cancer Care Services
Amanda Sutherland	Quality & Safety Officer, Cancer Care Services
Emilly Egan	Nurse Educator, Cancer Care Services
Dr Glen Kennedy	Executive Director, Cancer Care Services
Dr Melissa Eastgate	Medical Oncologist, Cancer Care Services
Lee Jones	Statistician, Queensland University of Technology
Dr Elise Button	Research Fellow, Queensland University of Technology

Royal Brisbane and Women's Hospital Contact Persons: Dr Nicole Gavin and Francesca Boyte

Human Research and Ethics Committee: RBWH HREC 68664

What does my participation involve?

You are invited to take part in this research which aims to investigate whether preparing your intravenous (IV) administration sets (known as an IV line) with monoclonal antibodies before they commence, will reduce chair time in the outpatient setting. Monoclonal antibodies are a type of cancer treatment designed to activate your immune system to fight cancer cells. Your doctor will have explained this to you before starting your treatment. Priming IV lines with monoclonal antibodies is a simple intervention that may positively impact patient outcomes. We hope this procedure may decrease the time you spend in the chair when you come to receive your treatment. This will decrease wait times and hopefully improve patient satisfaction. When the IV line is not primed with the monoclonal antibody before commencing your treatment, you will be receiving only normal saline or a compatible fluid for a period before being exposed to the drug. This can lead to increased time spent in the chair receiving your treatment. The research team wants to understand if this practice safely deceases the time you spend in the chair.

This Participant Information Sheet and Consent Form tells you about the research project. It explains why priming the IV line before you start receiving your medication could reduce the time you spend in the unit. This will help you decide if you want to take part in the research.

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

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

If you decide you want to take part in this research project, we ask you to sign the consent form. By signing it you are telling us that you:

- Understand what you have read
- Consent to take part in the research project
- Consent to the tests and research that are described
- Consent to the use of your personal and health information as described
- Acknowledging that you are aware that participation in this research is voluntary and will not affect the care that you receive

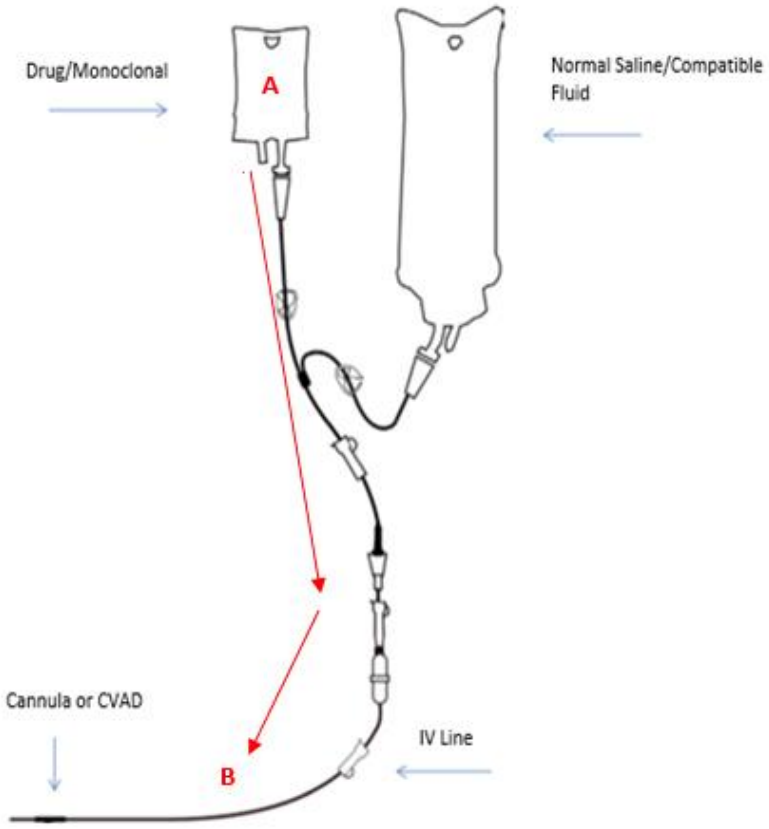
Participation in this research is voluntary. This information sheet has been provided to you to allow you to give fully informed consent. You should keep a copy of this signed sheet (provided) for your future reference.

How does it work, and what is the purpose of this research?

The research team want to ensure that you only spend the time necessary in the outpatient unit for your treatment. Before you are connected to an IV line, it is primed with normal saline or a compatible fluid to prevent the introduction of air. Once the IV line is connected to you, the drug you are receiving is then attached to the IV line. The drug is then primed from point A to point B (refer to figure A). If the IV line is not primed with the drug before it starts, you can be receiving the normal saline or compatible fluid for a period before receiving the drug. This can increase the time you spend in the bed/chair. This is standard care and will be the control group.

Priming the IV line with the drug, before it is commenced, will decrease the time you spend in the chair and allow nursing staff to monitor when you begin to receive the drug. This will be the intervention group. This study will allow for a more accurate understanding of the time spent in the chair/bed and when you begin to receive the drug.

Figure A.



What does participation in this study involve?

There will be no change to your treatment. The administration set (also the IV line) that delivers your treatment, will be primed with the drug in the intervention group or normal saline in the control group.

What do I have to do?

A member of the study team will talk to you about the study and confirm that there are no reasons that would prevent you from participating. We will then give you some written information, time to think and ask questions. Then, if you are happy to enter the study you will need to sign a consent form.

Do I have to take part in this research?

Participation in any research project is completely 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 and your relationship with the hospital. We encourage you to take time to consider participating. You may find it beneficial to discuss this study with your family.

What are the benefits of taking part?

Aside from reduced time you spend in the chair, there will be no direct benefit to you from your participation in this research. However, your participation in the trial and the data that we collect as a result may help us to improve treatment for other patients and improve wait times.

What are the possible risks and disadvantages of taking part?

There is a potential to react to the monoclonal antibody that you are receiving. These reactions are possible and have no relation to the study. These may occur whether you are participating in this study or not. Reactions are appropriately managed by the nursing staff in the Oncology Day Therapy Unit or Oncology Procedure Unit.

What if I want to withdraw from this research study?

If you decide to withdraw from this research project, please notify a member of the research team.

If you do withdraw your consent during this research project, you are given the option to either
a) consent to the retention of all personal information by the research team collected for the purpose of this research project, or
b) consent to the removal and destruction of all personal information collected for the purpose of this research project, in accordance with National Health and Medical Research Council (NHMRC) and National Statement on Ethical Conduct in Human Research (2007) guidelines

Will my details be kept confidential?

By signing the consent form, you agree to the research team 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 for the purpose of research. By signing the consent form, you agree to the research team accessing health records if they are relevant to your participation in this research project.

Your health records and any information obtained during the research project are subject to inspection for the purpose of verifying the procedures and the data. This review may be done by the relevant authorities, the institution relevant to this Participant Information Sheet or as required by law. By signing the Consent Form, you authorise release of, or access to, this confidential information to the relevant research personnel and regulatory authorities as noted above.

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.

Information about your participation in this research project may be recorded in your health records. In accordance with relevant Australian privacy and other relevant laws, you have the right to request access to the information collected and stored by the research team about you. You also have the right to request that any information with which you disagree be corrected. Please contact the research team member named at the end of this document if you would like to access your information.

Complaints and compensation

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. Participation is voluntary with no remuneration.

Ethical guidelines

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 The Royal Brisbane and Women's Hospital.

This project will be carried out according to the National Statement on Ethical Conduct in Human Research (2007). This statement has been developed to protect the interests of people who agree to participate in human research studies.

Further information and who to contact

If you have any questions about the study, we hope and expect that you will ask us. If you have any questions, please contact Nicole Gavin, Nurse Researcher, Cancer Care Services, Royal Brisbane and Women's Hospital, on 07 3646 5833.

Should you wish to discuss the research with someone not directly involved, in particular in relation to matters concerning policies, information about the conduct of the study or your rights as a participant, or should you wish to make an independent complaint, you can contact the Coordinator or Chairperson of the Human Research Ethics Committee, Royal Brisbane and Women's Hospital, Butterfield Street, Herston 4029 or telephone 07 3646 5490, or email RBWH-Ethics@health.qld.gov.au. For any research related complaints, you can contact the Research Governance Officer at the Royal Brisbane and Women's Hospital via telephone on 07 3646 8579 or via email at RBWH-RGO@health.qld.gov.au. If you have any concerns related to clinical care procedures, please contact the Royal Brisbane and Women's Hospital Patient Liaison Service via telephone on 07 3646 8216 or via email at RBWH-pls@health.qld.gov.au.

This document in no way limits your rights by law from any damage that might arise from negligence on the part of the investigators. You should keep a copy of this form provided. This information has been provided to allow you to give informed consent.

A RANDOMISED CONTROLLED TRIAL ASSESSING WHETHER PRIMING INTRAVENOUS ADMINISTRATION SETS WITH MONOCLONAL ANTIBODIES WILL REDUCE CHAIR TIME IN THE OUTPATIENT SETTING

PARTICIPANT INFORMATION, CONSENT & REVOCATION

ROYAL BRISBANE AND WOMENS HOSPTIAL

(Attach to Participant Information)

Thank you for agreeing to participate in this research study. You will help to provide valuable information that will help us to deliver safe and evidence-based care.

I have had the contents of this information sheet explained to me and I have been provided with a copy. I agree to be enrolled in the study and understand that I will be receiving the monoclonal antibody via either a) a drug primed administration set or b) a non-drug primed administration set.

Please read the following carefully and sign below if you agree with the statements and are happy to participate in the study.

1. I have read and understood the information sheet and consent form.
2. I have had the opportunity to ask questions about the study and these have been answered to my satisfaction.
3. I understand that this project is for research and that I may not benefit directly.
4. I have been informed that the information collected about me in this study will remain confidential and will be adequately safeguarded, and that when results are published, they will be presented in such a way that I cannot be identified.
5. I give permission for authorised study personnel to extract details that pertain to this study from my hospital medical record.
6. I understand that I am free to withdraw my consent (or consent for my carer to participate) and to discontinue participation at any time without comment, and with no effect on my treatment or my relations with staff at the Royal Brisbane and Women's Hospital in any way.

7. I understand that if I have any questions or comments about the study at any time I may contact Nicole Gavin on 07 3646 5833 or at nicole.gavin@health.qld.gov.au. If I have any complaints about the ethical conduct of the study, I may direct these to the Coordinator or Chairperson of the Human Research Ethics Committee on 07 3646 5490 or at RBWH-Ethics@health.qld.gov.au.

   I can also contact the QUT Research Ethics Advisory Team on +61 7 3138 5123 or email humanethics@qut.edu.au.

I would like a copy of the research results to be sent to me at the end of the trial:

Tick Box √ (Whichever is applicable)

Yes ☐

No ☐

Email/address for the report to be sent: _____

Name: _____ Signature: _____ Date: __/___/____

Enrolled by: _____ Signature: _____ Date: __/___/____

A RANDOMISED CONTROLLED TRIAL ASSESSING WHETHER PRIMING INTRAVENOUS ADMINISTRATION SETS WITH MONOCLONAL ANTIBODIES WILL REDUCE CHAIR TIME IN THE OUTPATIENT SETTING

PARTICIPANT INFORMATION, CONSENT & REVOCATION

ROYAL BRISBANE AND WOMENS HOSPTIAL

(To be used for participants who wish to withdraw from the project)

(Attach to Participant Information)

I hereby wish to WITHDRAW my consent to participate in the research project described above. I understand that such withdrawal WILL NOT jeopardise any treatment or my relationship with staff at the Royal Brisbane & Women's Hospital.

Tick Box √ (whichever is applicable)

◯ I consent to the retention of all personal information collected during the period of my participation for inclusion in the analysis of this research.

◯ I request the removal of all personal information collected during the period of my participation in this study from the research analysis.

Participant's name (printed): _____

Signature: _____ Date: __/___/____

Please send to:

Dr Nicole Gavin,
Nurse Researcher,
Nursing and Midwifery Research Centre,
Level 2, Building 34
Centre for Clinical Nursing
Royal Brisbane and Women's Hospital,
Herston, QLD 4029