The Research Team	
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Assoc Prof Jarad Martin	4014 3631
Dr Geetha Govindarajulu	4014 3631
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Dr Anne Capp	4014 3631
Laura O'Connor (Research Radiation Therapist)	**4014 3168**

Study of MRI for Complex Pelvis planning with Synthetic CT

INFORMATION FOR PARTICIPANTS

Introduction

You are invited to take part in a research study looking at better ways to plan treatment for patients who need to have radiotherapy as part of their treatment. In particular we want to determine whether radiotherapy treatment for rectum, anal canal, cervix and endometrial cancer can be planned using Magnetic Resonance Imaging (MRI) scans instead of Computed Tomography (CT) Scans.
This research is being conducted by Laura O'Connor as part of her Higher Degree by Research Studies at the University of Newcastle. She is supervised by Professor Peter Greer (Calvary Mater Hospital), Dr Jarad Martin (Calvary Mater Hospital), Associate Professor Helen Warren-Forward (University of Newcastle) and Dr Jason Dowling (CSIRO).

What is the research about?

Radiation therapy treatment requires careful planning and calculation to determine how your treatment will be delivered. This process ensures the delivery of a large amount of radiation to the treatment site while limiting the amount of radiation to healthy organs and tissue surrounding the treatment site. Currently this treatment planning is carried out using a CT scan.

This study aims to determine if it is feasible to use an MRI scan, instead of a CT scan for planning. This change is expected to improve the accuracy of the planning as well as reduce patient's exposure to ionizing radiation. This requires developing a program/method which allows the calculation of radiation dose from the MRI scan. The CSIRO will investigate their computer based methods to achieve this.

Where is the research being done?

This study is being conducted within the Calvary Mater Hospital Newcastle by:
- Laura O'Connor, Research Radiation Therapist, Radiation Oncology who is undertaking a research higher degree in at the University of Newcastle, Ms O'Connor will be supervised by:
- Professor Peter Greer, Principle Physicist, Radiation Oncology
- Dr Jarad Martin, Radiation Oncologist, Radiation Oncology

- Jason Dowling, Biomedical Informatics, CSIRO
- Associate Professor Helen Warren-Forward, Medical Physicist, School of Health Sciences, University of Newcastle

The study is supported by a research grant from the Calvary Mater Newcastle Hospital.

Who can participate in the research?

This research study is suitable for men undergoing radiotherapy at the Calvary Mater Newcastle for rectal or anal canal cancer and women undergoing radiotherapy at the Calvary Mater Newcastle for rectal, anal canal, cervix or endometrial cancer. If you are unable to have MRI scans because you have metal implants or suffer from claustrophobia, then unfortunately this study may not be suitable for you. If this is the case, then you will receive the standard treatment.

What Choice do you have?

Participation in this research is entirely your choice. Only those people who give their informed consent will be included in the project. Whether or not you decide to participate, your decision will not disadvantage you, and it will not affect your medical treatment or the relationship with the staff who are caring from you. If you do decide to participate, you can withdraw from the research without giving a reason at any time before undertaking the MRI scan.

What would you be asked to do if you agree to participate?

If you agree to participate in this study, you will be asked to sign the Participant Consent Form and then undergo a MRI Scan. This scan will occur following your standard CT scan. The MRI scan will not affect your usual planning and treatment, thus you will receive the standard radiotherapy treatment that the doctor has recommended.

Your treating Radiation Oncologist has provided you with this information form. You will be given time to consider participation in this study and, after a couple of days, one of the research team will contact you to answer your questions. If you choose to participate you will be asked some questions to assess if participating in this research is suitable for you. If the research is suitable for you, you will be asked to attend a half hour planning MRI scan. This planning MRI scan will take place at Calvary Mater Newcastle and will be booked for you on the same day as your planning CT scan. The additional MRI is not standard practice for patients. We will ask you to give verbal consent over the phone for us to book your MRI appointment. We will then ask you to give written consent by signing the consent form on the day of your planning scan.

If you are a participant in the research, your MRI and CT scans will be de-identified and sent to the CSIRO in Brisbane for the purpose of this research. You cannot be identified from these scans as all your personal information will be removed before they are sent.

What are the risks and benefits of participating?

Risks

The risks of participating in this study are:

Radiotherapy Treatment
There are potential side-effects involved with radiotherapy to the pelvis. As the radiotherapy treatment that you receive is standard practice, there would be no greater risk of potential radiotherapy side-effects for you on the study.

MRI
There are no health risks associated with MRI scanning, provided you do not have any metallic objects in your body with a strong magnetic charge (e.g. pacemaker, hearing implants) and/or you are pregnant. The space inside the scanner is quite small, so patients suffering from claustrophobia (severe discomfort in enclosed places) are advised not to participate in this study. One of the research team members will help you to fill out a screening questionnaire to ensure it is safe for you to have the scan.

Benefits

While we intend that this research study furthers medical knowledge and may improve radiotherapy treatment in the future, it will not be of direct benefit to you.

Compensation for injuries or complications

If you suffer any injuries or complications as a result of this study, you should contact the study doctor as soon as possible, who will assist you in 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.

In addition, you may have a right to take legal action to obtain compensation for any injuries or complications resulting from the study. You do not give up any legal rights to compensation by participating in this study.

Will the study cost you anything?

Participation in this study will not cost you anything, nor will you be paid. There will be no additional visits to the hospital however at routine visit costs may be incurred for parking.

How will your privacy be protected?

All the information collected from you for the study will be treated confidentially, and only the researchers named above will have access to it. The study results may be presented at a conference or in a scientific publication or a research thesis, but individual participants will not be identifiable in such a presentation.

Personal information will be accessed, used and stored in accordance with Commonwealth Privacy Laws and the NSW Health Records and Information Privacy Act 2002.

Further Information

When you have read this information, a member of the study team will discuss it with you further and answer any questions you may have. If you would like to know more at any stage, please feel free to contact the Research Radiation Therapist or your treating Doctor on the numbers listed at the top of the first page of this document.

This information statement is for you to keep. Thank you for considering this invitation.

Complaints about this research

This research has been approved by the Hunter New England Human Research Ethics Committee of Hunter New England Local Health District, Reference 17/06/21/3.02

Should you have concerns about your rights as a participant in this research, or you have a complaint about the manner in which the research is conducted, it may be given to the researcher, or, if an independent person is preferred, to Dr Nicole Gerrand, Manager, Research Ethics and Governance Unit, Hunter New England Human Research Ethics Committee, Hunter New England Local Health District, Locked Bag 1, New Lambton NSW 2305, telephone (02) 49214950, email HNELHD-hrec@hnehealth.nsw.gov.au

The conduct of this study at the Calvary Mater Newcastle has been authorised by the National Board of the Little Company of Mary Health Care. Any person with concerns or complaints about the conduct of this study may also contact the Research Governance Officer on 4921 4950 and quote reference number SSA/17/HNE/376

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PARTICIPANT CONSENT FORM

I have read and understand that the study will be conducted as described in the Information Statement, a copy of which I have retained.

I have been made aware of the procedures involved in the study, including any known or expected inconvenience, risk, discomfort or potential side effect and of their implications as far as they are currently known by the researchers.

I understand that my participation in this study will allow the researchers and others, as described in the Information Statement, to have access to my medical record, and I agree to this.

I agree to participate in this study and understand that I can withdraw at any time before receiving the MRI scan

I understand that my personal information will remain confidential to the researchers.

I have had the opportunity to have questions answered to my satisfaction.

I hereby agree to participate in this research study.

NAME: _____

SIGNATURE: _____

DATE: _____

Declaration by person conducting the consent process

I, the undersigned, have fully explained this research to the patient named above.

NAME: _____

SIGNATURE: _____

DATE: _____