The CANCAN Study

A cross-sectional study of the relationship between iron deficiency anaemia and chronic pain in patients presenting to a multidisciplinary pain centre in a tertiary referral teaching hospital

PARTICIPANT INFORMATION SHEET/ CONSENT FORM

Royal Brisbane and Women's Hospital

Royal Brisbane and Women's Hospital Principle Investigator: Associate Professor Kerstin Wyssusek (07 3646 3104)
Royal Brisbane and Women's Hospital Chief Investigator: Associate Professor Paul Gray, Dr Sandra Concha Blamey, Professor Andre Van Zundert.
Royal Brisbane and Women's Hospital Associate Investigators: Ms Christine Woods (07 3646 6811, Heather Reynolds.
HREC Number: HREC / 2019 / RBWH/ 58663

You are invited to take part in this research, A cross sectional study of iron deficiency anaemia and chronic pain study. This is because you are presenting to the Professor Tess Cramond Multidisciplinary Pain Centre at the Royal Brisbane and Women's Hospital (RBWH). This research project aims to assess the prevalence of anaemia and iron deficiency and explore the relationship between iron deficiency anaemia and pain. Participation is completely voluntary, and you may refuse/withdraw your consent at any time.
You will be given a copy of the Participant Information Sheet and Consent Form to keep. We would encourage you to keep a copy of this sheet for your future reference.

Description of research study
Approximately 30% of the world's population suffer from anaemia, a condition characterised by decreased levels of red blood cells or haemoglobin in the blood, resulting in reduced capacity to carry oxygen. Iron deficiency anaemia is the most common type of anaemia and is a significant health problem both in Australia and worldwide. There are many misconceptions in the diagnosis and management of iron deficiency, and this is especially prevalent in people with chronic conditions.
The symptoms of iron deficiency can be debilitating and may exacerbate these conditions.
The pain that you may experience could contribute to a higher prevalence of iron deficiency in chronic patients, but there are been no studies to date regarding this. This project involves being approached by training research personnel when you attend your outpatients' appointment in the Pain Centre.
Information will be collected from your medical chart including basic demographic details, clinical details including; pain status, medications, current care details, diet, and a blood test.

Why have you been chosen
You are invited to participate in this study because you have been identified as attending the Pain Centre for treatment of a chronic pain condition.

What we will ask you to do
a) After reading through this information sheet you will be asked to consent if you agree
b) If you agree to participate in this study, the research nurse will record your demographic details and blood sampling (pathology). We will then measure your pain on the visual analogue scale and fatigue levels measured with the FACIT score. This data will be used to determine the relationship between iron deficiency anaemia and chronic pain.
c) (include about Redcap?)

d) All data will be deidentified with a unique study number for each participant. (To be included: Subject to your approval, this data may be used for future research studies by the investigators, subject to further Human Research Ethics Committee approval)

Risks to you

Having a blood sample taken may cause some discomfort, bruising, minor infection or bleeding. If this happens, it can be easily treated, and any adverse events will be addressed and reported immediately to the HREC at RBWH.

Benefits to you

The results from your blood sample may reveal you are anaemic with or without iron deficiency and a referral letter will be sent to your treating GP for follow up and investigations. It is anticipated that the results from this pilot trial will provide pertinent data for chronic pain patients and the prevalence of iron deficiency anaemia to improve health related quality of life, and to reduce pain and fatigue levels.

Confidentiality

The trained research personnel will allocate all participants a unique study number and all data will be deidentified. Your data will be stored using a Research Electronic Data Capture Platform, also known as REDCAP. REDCAP will be used for data entry and downloading data for analysis. Combined patient results will be presented in scientific journals and conferences. You will not be referred to by name and your personal identity will not be revealed in any publication or presentation. Research records will be destroyed 15 years after the study as per the Royal Brisbane and Women's Hospital guidelines.

Choosing to participate or not

Your participation is entirely voluntary and if you decide not to participate this will not affect your medical care, or treatment by hospital staff in any way. If you choose to participate, you are free to withdraw your consent and to discontinue participation later, by telling the research staff.

If you have any questions

If you have any questions now, or later, we hope and expect you to contact us. Please contact the Anaesthetic Research Nurses on (07) 3646 8811 (or email: anaesresearch@health.qld.gov.au) and we will be happy to answer your questions.

Other issues

This document in no way limits your rights at law from any damage that may arise from negligence on the part of investigators.

Other relevant information about this project

In total there will be 80 patients taking part in this study at the Royal Brisbane and Women's Hospital

Who is organising and funding the research

The study is currently being funded by Internal department funding at the Royal Brisbane and Women's Hospital. No member of the research team will receive a personal financial benefit from your involvement in this research project (other than their ordinary wages).

Who has reviewed the study

All research in Australia involving humans is reviewed before a study starts by an independent group of people called a Human Research Ethics Committee (HREC). This study has been reviewed and approved by the HREC/2019/RBWH/58663 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.

Form for Consent to Participation

Title	*A cross-sectional study of the relationship between iron deficiency anaemia and chronic pain in patients presenting to a multidisciplinary pain centre in a tertiary referral teaching hospital*
Short Title	*A cross-sectional study of iron deficiency anaemia and chronic pain (CANCAN)*
Protocol Number	*Version 1, Dated 4th November 2019*
Investigators	*Associate Professor Kerstin Wyssusek* *Associate Professor Paul Gray* *Dr Sandra Contra Blamey* *Professor André van Zundert*
Associate Investigators	*Ms Christine Woods* *Ms Heather Reynolds*
Location	*The Royal Brisbane and Women's Hospital*

Declaration by Participant

I have read the Participant Information Sheet Version 1 dated 4th November 2019 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 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. I understand that, if I decide to discontinue the study treatment, I may be asked to provide follow-up information to allow collection of information regarding my health status. Alternatively, a member of the research team may request my permission to obtain access to my medical records for collection of follow-up information for the purposes of research and analysis.

Name of Participant (please print) _____

Signature _____ Date_____

Declaration by Study Doctor/Researcher

I confirm that the participant has been given a verbal explanation and written information on the research project, its procedures and risks and I believe that they have understood that explanation.

Name of Study Doctor/
Researcher (please print) _____

Signature _____ Date_____

Form for Withdrawal of Participation

Title	*A cross-sectional study of the relationship between iron deficiency anaemia and chronic pain in patients presenting to a multidisciplinary pain centre in a tertiary referral teaching hospital*
Short Title	*A cross-sectional study of iron deficiency anaemia and chronic pain (CANCAN)*
Protocol Number	*Version 1, Dated 4th November 2019*
Investigators	*Associate Professor Kerstin Wyssusek* *Associate Professor Paul Gray* *Dr Sandra Contra Blamey* *Professor André van Zundert*
Associate Investigators	*Ms Christine Woods* *Ms Heather Reynolds*
Location	*The Royal Brisbane and Women's Hospital*

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 The Royal Brisbane and Women's Hospital.

I agree to the use of my data that was collected prior to my withdrawal of consent.

Yes / No (please circle)

I agree to the study investigators continuing to collect information about me, specifically in relation to my progress in hospital.

Yes / No (please circle)

Name of Participant (please print) _____

Signature _____ Date_____

Declaration by Study Doctor/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.

Name of Study Doctor/
Researcher (please print) _____

Signature _____ Date_____