

CTNZ Newsletter

Sep 2018 | **Quarterly newsletter** | Issue 36

PantoCIN Study



Breast Cancer
Foundation NZ



A phase II, randomised, double-blinded, placebo controlled, crossover trial to assess Pantoprazole's effectiveness as prophylaxis against delayed chemotherapy-induced nausea and vomiting (CINV) in patients receiving adjuvant or neoadjuvant breast cancer chemotherapy

CTNZ is very pleased to announce a new trial in its portfolio - the PantoCIN Study. The aim of this study is to determine the anti-emetic activity of Pantoprazole in the prophylaxis of delayed chemotherapy induced nausea and vomiting in patients undergoing adjuvant or neo-adjuvant breast cancer treatment. If this trial shows improved control of nausea in patients receiving chemotherapy for breast cancer, the results may also be applicable to other moderately emetogenic and highly emetogenic chemotherapy regimens in oncology. The results of this trial have the potential to inform further clinical trials in breast and other cancers, as well as improve our understanding of the mechanisms behind delayed chemotherapy induced nausea and vomiting.

Funding for the PantoCIN Study has very kindly been awarded from Breast Cancer Foundation New Zealand and Breast Cancer Trials (formally Australia New Zealand Breast Cancer Trials Group [ANZBCTG]). This will be a three-year national study across 8-9 sites. The plan is to get the study open for recruitment in March next year. The lead investigators are Drs Richard Isaacs and Navin Wewala from Palmerston North Hospital and we are very happy to be working with such committed investigators and a dedicated team. You may have heard Navin present this study in our new concepts session at our Annual Scientific Meeting last year.

ANNUAL SCIENTIFIC MEETING

Monday 3rd December 2018

Domain Lodge, 1 Boyle Crescent, Grafton, Auckland

Please come and join us at Cancer Society Auckland and Northland's headquarters to celebrate 15 years of Cancer Trials New Zealand being in operation. Celebrating with our core funders since the outset is very fitting. We have a very eminent guest speaker Professor Chris Karapetis (see page 2 for more details) and the finalised programme will be circulated shortly. If you have not already registered please click [here](#) to be taken to the registration page.

We look forward to joining in with our celebrations and for what will be a very interesting and informative day.





NEWS

CTNZ is very pleased to introduce **Professor Chris Karapetis** as the invited speaker for their Annual Scientific Meeting in December. Chris will be talking about trials and research that he's been involved with over the years in his presentation **"Trials and Tribulations of a Clinical Researcher"**



Professor Chris Karapetis is Network Director for Cancer Services in the Southern Area Local Health Network of Adelaide, and Head of the Department of Medical Oncology at the Flinders Medical Centre. He is also the Director of Clinical Research in Medical Oncology at the Flinders Medical Centre and the Flinders Centre for Innovation in Cancer, Flinders University. He practices as a senior consultant medical oncologist at the same institution where he was instrumental in the establishment of a Clinical Research Unit.



Flinders Centre
for Innovation
in Cancer



Professor Karapetis has been the principal investigator on over 150 clinical trials. His interest in clinical research developed following a research fellowship at Guy's Hospital in London. He has established research interests in the areas of lung cancer, gastrointestinal malignancy, molecular targeted therapies, predictive biomarkers, epidemiology and clinical research methodology. He is an active contributor to clinical research conducted through the Australian Lung Trials Group and the Australasian Gastrointestinal Trial Group. He has served on NHMRC Grant Review Panels through 2015 to 2017. He is the current chair of the Medical Oncology Group of Australia and serves on the ACORD executive committee. He was the convener of the 2007 Annual Scientific Meeting of COSA and the 2011 MOGA ASM when these meetings were held in Adelaide. He is a member of editorial boards and has acted as a reviewer for several high-impact factor medical journals. Professor Karapetis has published over 130 scientific papers in peer-reviewed scientific journals.



CANCER
RESEARCH
TRUST
NEW ZEALAND



CTNZ has submitted **three funding applications**. Two applications to the Cancer Research Trust's Special Purpose Grant round, one for a two day consumer representatives training session (open to all cancer consumer reps in New Zealand), the other for a concept development workshop. We are also part of an HRC Feasibility application with Professor Sandie McCarthy (School of Nursing, University of Auckland). All of these applications have been possible through strong collaborations.

We will let you know the outcomes of these applications in due course.

Remember if you have any ideas for trials, studies, training or programmes please contact the CTNZ Research Operations Manager, Sarah Benge (s.benge@auckland.ac.nz)



CURRENT TRIALS and STUDIES

KISS

Recruitment for the KISS study is ongoing at six treating centres across New Zealand. Currently, we have 13 participants enrolled on the study. We are currently organising the necessary approvals to include North Shore, Taranaki and Hawkes Bay Hospitals as additional sites for the study. Discussions with the Australasian Leukaemia and Lymphoma Group to extend the study to Australian sites are ongoing.

Dunedin	3
Christchurch	2
Wellington	0
Taranaki	In set up
Palmerston North	2
Hawkes Bay	In set up
Middlemore	2
Auckland	4
North Shore	In set up
TOTAL	13

Our recruitment target is 100 patients with newly diagnosed chronic myeloid leukaemia. The study is investigating the efficacy and safety of a new treatment plan using two drugs called tyrosine kinase inhibitors (TKIs) – dasatanib and imatinib. The study aims to determine whether there is an advantage to starting people on the newer, more potent TKI (dasatanib) in order to achieve a faster remission and then to switch to the older TKI (imatinib) in people who reached a safe level of remission within one year of treatment on the dasatanib.

For further information about the KISS study, please contact Kate: kate.gorton@auckland.ac.nz

THYmine 2

The THYmine 2 study has 26 patients enrolled so far. Recruitment rate is slower than anticipated so we are extending the study to three additional sites. Canopy Cancer Care (Auckland) was opened for recruitment in mid August. We are hoping to open Tauranga and Dunedin hospitals in the next couple months.

Dunedin	In set up
Tauranga	In set up
Auckland	26
Canopy Care (Auckland)	1
TOTAL	27

The study aims to recruit 200 patients with gastrointestinal or metastatic breast cancer for whom the use of a schedule containing fluoropyrimidine (Capecitabine or 5-FU) is planned as a monotherapy or in combination.

For further information about the THYmine2 Study, please contact Rebecca: r.hu@auckland.ac.nz

MELVAC

The last patient's last visit was completed at the end of August as planned. A total of 31 participants have completed the phase II study. All vaccinations have gone smoothly. The team is now cleaning the data in preparation for the database lock in November. We are planning to start the statistical analysis shortly after that.

For further information about MELVAC, please contact Rebecca: r.hu@auckland.ac.nz



CURRENT TRIALS and STUDIES (cont'd)

PROSPER

This project introducing genomics to clinic is recruiting well with over 35 patients recruited. We are about to start the analysis of the tumour samples and hope to have preliminary data very soon. Feedback from patients has been fantastic and we look forward to seeing the results unfold. A Study Management Committee meeting is scheduled for mid October and an interim report has gone to the funder, The Li Family Trust.

For further information, please contact either Michelle: MiWilson@adhb.govt.nz or Lou (CTNZ): louise.clement@auckland.ac.nz

PantoCIN

This double blind placebo controlled trial will be sponsored by the University of Auckland with the lead investigators based at Palmerston North Hospital (MidCentral DHB). The plan is to run this trial out of 8-9 sites across New Zealand, including regional centres. 160 participants are required, men and women with adjuvant or neo-adjuvant breast cancer receiving specific regimens of chemotherapy. Trial participation for the patients is very short, the Pantoprazole and Placebo are taken for five days at the beginning of cycles 1 and 2 in a crossover design. This simple study with a short duration of medication is hoped to have a positive influence on recruitment and retention. The protocol has almost been finalised and the database build will start very soon. We plan to have the trial open for recruitment in March 2019.

For further information, please contact Lou: louise.clement@auckland.ac.nz

SOLD

Annual follow-up continues for all patients on this study.

For further information, please contact Jade: j.scott@auckland.ac.nz

For information about the Pink Star Walk please click [HERE](#)



SATURDAY
27TH OCTOBER 2018



AUCKLAND DOMAIN



SATURDAY
3RD NOVEMBER 2018



FRANK KITTS PARK — WELLINGTON WATERFRONT



SATURDAY
10TH NOVEMBER 2018



NORTH HAGLEY PARK — THE ENTERTAINMENT TRIANGLE, ARMAGH STREET



New people joining CTNZ

In September we welcomed three new people to the Team

Lusiane Belaus (Luzi) joins us as our new Clinical Trials Data Manager and she will take over the role fully when Gwladys leaves us in October. Luzi has very recently arrived in New Zealand having emigrated with her family from Israel. Luzi’s previous role was with Teva Pharmaceuticals, she has over 9 years’ experience in global clinical trials, including a variety of therapeutic areas. She has led Clinical Data Management activities in the Biometrics Department for over 20 studies, as a line manager and CRO manager. More recently, as a Clinical Project Manager, Luzi worked in the development and execution of three anti-CGRP phase III studies with ePRO and Digital Wearable endpoints. Luzi holds an MBA in Biomedical Management focused on Clinical Trials from The College of Management Academic Studies in Israel and Medicine Studies from Barceló Foundation in Argentina.



Louise Clement (Lou), another very recent émigré, joins us from England as a Clinical Trials Manager, primarily for our new trial, the PantoCIN Study. Lou graduated from King’s College London with a degree in Human Biology and then studied for a Postgraduate Diploma in Developmental Biology at University of Sussex. She has worked in clinical trials since 2007, beginning in oncology at the Medical Research Council, Clinical Trials Unit in London and continuing in academic research, within a range of specialities. Most recently, she worked for the National Institute for Health Research in England as a regional Research Facilitator in primary care.

Robert Cartwright joins us as our SAS Programmer and he will be involved across all of our trials. Robert graduated from The University of Auckland in 2016 with a Bachelor of Science in Biomedical Science, and has recently completed a Master of Biomedical Science at The Liggins Institute. In his Masters, Robert investigated the influence of fetal growth restriction on the effects of repeat antenatal corticosteroid therapy for preterm birth. Robert is also an active Volunteer Ambulance Officer with St. John Ambulance. As our SAS programmer, Robert will be working alongside Luzi, writing and running SAS programmes to compliment our ALEA electronic data capture system.



Saturday 24 November 2018 | Auckland, NZ



Cancer Society
Te Kāhui Matepukupuku
o Aotearoa
With thanks to
the Cancer Society
Auckland and Northland

To sign up or for more
information, please click [HERE](#)

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