

Summer is upon us and ice cream has been all around us lately with ReCharge enjoying National and International fame. Following an official release to the media about this novel ice cream trial, ReCharge was included as a news item on TV1, TV3 and Prime news, and an interview was featured on Sunrise. There was extensive coverage in both National and International print and online media, with coverage extending as far as the New York Times and BBC world. The New Scientist will also be running an upcoming article about the development of the ReCharge product.

The release generated a large amount of interest from patients throughout the country, and has increased general awareness of the trial. ReCharge is open to recruitment at Auckland, Palmerston North, Christchurch, Dunedin and Invercargill Hospitals. Since recruitment opened in August there have been 17 patients enrolled. Auckland is the highest recruiting site, with 13 patients so far. Well done, Auckland! We hope to have Wellington and Tauranga Hospitals open by Christmas, with Waikato to follow in the New Year. This trial is well placed for consideration at rural/satellite centres, with back-up from their regional cancer centres.

Remember ReCharge is open to patients with 1st, 2nd or 3rd line chemotherapy given as a 2 or 3 weekly regimen containing capecitabine, docetaxel, paclitaxel, 5FU or irinotecan (but not oxaliplatin) for advanced disease. Associate Professor David Perez is the study Chairperson, with Dunedin as lead centre.

Janie Proctor is the Trial Manager and Monitor at CTNZ. If you have any questions please contact Janie at +64 9 923 9643 or email j.proctor@auckland.ac.nz.

This trial is sponsored by LactoPharma (a joint venture of Fonterra and Auckland Uniservices Ltd.)



Directors Message



On behalf of the CTNZ operations team I would like to thank all investigators, research nurses, trial coordinators, supporters and patients for all their work this year. Collaborative clinical trials research is a complicated but vital link between the laboratory and clinical practice innovations. Looking back over this year I think we can take some pride in the progress we have all made however somehow it never seems enough - roll on next year!

I hope you all have a Merry Christmas and Happy New Year whether you are on holiday or 'holding the fort' at work. Best wishes ,

Nick

Australasian Co-operative Trials Groups

The Australia and New Zealand Melanoma Group (ANZMTG)

The ANZMTG was established in 1999 in response to the need to centrally promote and support melanoma clinical trials for investigators and consumers in Australia and New Zealand. ANZMTG aims to: foster collaboration and exchange of ideas between melanoma researchers and consumers; provide support to investigator-driven multi-centre clinical trials; and to become the single point of contact for sponsors and investigators wishing to undertake melanoma clinical trials in Australia and New Zealand.

ANZMTG is a Co-operative Trials Group of the Clinical Oncological Society of Australia (COSA) and is funded by Cancer Australia. The group is chaired by Professor John Thompson. There are currently two ANZMTG trials in the follow-up phase, three ANZMTG trials that are open and recruiting and several other projects in the pipeline.

ANZMTG is also focused on melanoma patient perspectives and are in the process of developing resources and initiatives to assist consumers becoming active and informed representatives in the development of trials.

The ANZMTG would like to encourage health professionals from New Zealand to join them, for better representation within the group. Melanoma researchers are also encouraged to submit melanoma trials proposal to ANZMTG Executive Committee for review and support, to allow better facilitation of the development of new melanoma trials. For more information and to apply for membership, please visit www.anzmtg.org.au or contact ANZMTG on anzmtg@usyd.edu.au or +61 02 9911 7352.

CYCLOX II Presentation at the 47th Annual Scientific Meeting of the Japanese Society of Oncology: A report from Dr Harvey

I recently returned from Japan where I was invited to present the CYCLOX II data at a Chugai sponsored symposium at the 47th Annual Scientific Meeting of the Japanese Society of Oncology. The presentation was very well received in Japanese (!) as the simultaneous translation was extraordinarily efficient.

Capecitabine + cyclophosphamide is a standard chemotherapy for metastatic breast cancer in Japan, though they only have single arm phase II studies, so were very interested in our randomised study. We have had several offers to collaborate with future studies from one group using intermittent capecitabine and cyclophosphamide and another group using both drugs continuously. I will continue to correspond with them and see good opportunities here.

The Japanese Phase II intermittent study manuscript has been submitted to



the Journal of Clinical Oncology. Ours will soon be ready, currently on draft 9!

COSA 2009 Annual Meeting

The 36th annual scientific meeting was held in November. The theme of this year's conference was 'awareness, access and action'. These themes mirrored a number of issues that CTNZ are currently exploring.

Awareness: Stephanie attended the workshop on consumer participation with a view to exploring the best way to involve consumers in the work of CTNZ. Access: Trials are not always easily accessible to patients for geographical, cultural and economic reasons. Initiatives were presented discussing equity of access to cancer services (including trials) for patients across Australia. This is an issue that CTNZ are already mindful of within the NZ setting. Action: In addition to focusing on the latest treatments the meeting presented an opportunity for Stephanie to catch up with the COSA executive officers network and in particular to discuss the comments received from NZ DHBs regarding the proposed NZ clinical trial agreement. This is now getting close to finalisation and Stephanie will be taking this forward and contacting those of you involved in this initiative shortly. It is hoped this will be a very positive action in 2010!

New Study - RAZOR

RAD001 and ZOledronic acid in Renal cell carcinoma patients with bone metastases - a randomised phase II trial



This study protocol has been developed by CTNZ and Dr Reuben Broom at Auckland City Hospital. The study has now been submitted to MREC for review and we are hoping to be open for recruitment in January 2010. If you are interested in your site participating in this study please contact Dr Broom (ReubenB@adhb.govt.nz) or CTNZ Research Manager Stephanie Pollard (s.pollard@auckland.ac.nz).

Brief Trial Updates

ASA404 Liver Impairment Study

This trial has been open in Auckland for several months, with 3 patients with normal hepatic function treated. Wellington are due to open any day now, pending ethics approval of local site documents. Protocol version 2 has just been approved by ethics. Novartis are currently in the process of opening International sites in Australia, France and Norway.

SIRFLOX

We currently have a total of 26 patients on study, with a fantastic 10 from Dunedin and 9 from Christchurch, along with 7 from Auckland. Due to a recent quiet patch however, we will need to pick up the pace again in the New Year to stay on target. Recently Dunedin received approval for local patients to be treated with SIRT at Dunedin Hospital by Dr Gabes Lau. Protocol version 6 is being forwarded from the sponsor for ethics submission.

SOLD

31 patients from 3 New Zealand sites have now been randomised into the study. Wellington was initiated at the end of September. International accrual has now reached 462.

Christmas Trial Cover

ASA404 Liver Impairment Study

Due to the closure of Auckland Clinical Studies Ltd no new patients will be able to go on trial in Auckland from 15th Dec - 10th Jan. All SAE's should be completed by the research nurses, and faxed directly to Novartis, with a copy going to CTNZ.

ReCharge

Between 24th Dec - 5th Jan Dr David Perez should be contacted directly by email: david.perez@otagodhb.govt.nz for protocol queries and exemption requests. Life threatening SUSARS/URGENT database issues ONLY should be phoned through to Janie on 021 424 759.

SIRFLOX

Any urgent queries between Dec 24 - Jan 11th should be directed to Dr Dragan Damianovich 021 978 222. SAEs should be completed by the research nurse and faxed directly to Sirtex, with a copy to CTNZ and Prof Findlay's signature to follow.

SOLD

Any eligibility/protocol queries should be directed to Dr Vernon Harvey. All SAEs should be faxed directly to Finland and CC'd to CTNZ as per usual.

New Staff

CTNZ would like to welcome Dr Sanjeev Deva, Medical Oncology Registrar from ADHB who is providing research time to CTNZ and the team. Just in time for the Christmas party!

Rotary Club of Birkenhead Dawn Walk for Prostate Cancer

Thank-you to everyone who joined in on this walk, proceeds to support prostate cancer research.



NZ Cancer Centre Staff Profile: Janie Proctor



Janie joined CTNZ in May of this year primarily as the Trial Manager/Monitor for the ReCharge Study. With a BSc in Chemistry and a MSc in Nutritional Science plus a background in oncology trials; this made Janie the ideal trial manager for ReCharge. Initially after her undergraduate degree she worked in the wine industry (which she ensures us is not as glamorous as it sounds), but an interest in nutrition led her to return to university to study nutrition.

Some of you may remember Janie from when she worked as a Clinical Trial Coordinator in Oncology Research at ADHB. During this time she worked on trials that included SATURN, TITAN, QUASAR 2 and GALES. She has since had a variety of research roles within The University of Auckland, most recently as Research Associate/ Unit Manager at the Human Nutrition Trial Unit. Other roles have included being a researcher in the field of Health Services/Programme Evaluation and Project Manager for the STAR Project, a national research project and scholarship fund. Janie is a keen runner (though she tells us the body is not always willing) and enjoys exercising in general. Surprisingly she has found that she has very green fingers when it comes to her vegetable garden, much to the envy of all the neighbours. She is slightly worried that she is seen as a bit of a mad cat woman.

Please note that CTNZ will be closed from 5pm on 23rd December to 9am on 5th January. Details for emergency cover for each trial are included in the trial summaries on page 3.

From all of us at CTNZ we wish you all a very Merry Christmas, Happy New Year and safe & enjoyable holiday period.

Seasons Greetings!



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