

The RAZOR Study

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



Trial Coordinator Steve Duffey hands Principal Investigator Dr Reuben Broom the randomisation envelope for the first patient.

Our newest study led by Dr Reuben Broom opened to recruitment at the end of January 2010 at Auckland City Hospital and has already randomised 5 patients, with a further 3 patients in screening after agreeing to participate. As evidenced by this rapid accrual, patient acceptability seems very high.

Bone metastases are a devastating complication for many patients with renal cell carcinoma. This trial aims to investigate the effects of adding bone-specific therapy (with the bisphosphonate zoledronic acid) to targeted therapy for renal cell cancer (the oral m-Tor inhibitor RAD001). RAD001 has proven activity as 2nd-line treatment in renal cell carcinoma. This study is one of the first to use RAD001 in the front-line setting and all patients receive treatment with it until progression. The primary end-point is the change in the bone turnover marker urinary N-telopeptide, with secondary end-points including; pain scores, skeletal-related events, response rates and progression-free survival. This is a New Zealand developed trial, which has attracted international interest. CTNZ is keen to bring on other New Zealand sites. For further information, please contact the Trial Coordinator Steve Duffey at s.duffey@auckland.ac.nz or the Principal Investigator Dr Broom at ReubenB@adhb.govt.nz.

Directors Message

The team at CTNZ and myself would like to sincerely congratulate Vernon Harvey on his well deserved appointment as an officer of the New Zealand Order of Merit for services to medicine, particularly oncology research. Vernon has made, and continues to make, a wonderful contribution to clinical trials.

Another year is rapidly flying by with lots of activity in the clinical research arena. We are pleased to launch the RAZOR study conceived by Dr Reuben Broom and already recruiting. Our studies continue to recruit - some better than others - the others giving us much to think about in terms of novel recruitment strategies. I would encourage you to remember that studies asking good questions are not necessarily easy to recruit to so please keep looking for those patients. If you have any questions about studies that might be of interest to you please do not hesitate to contact me or the team.

You will be aware that there is a parliamentary select committee hearing on clinical trials. We have made a submission and hope that others have as well. This is a key opportunity to highlight the importance of clinical trials in New Zealand.

Finally, thank you as always to all our colleagues around the country for supporting our trials.



Up-coming Meetings

New Zealand Society for Oncology 2010 Annual Conference

3-5 May, The Langham Hotel, Auckland

This years annual NZSO conference is rapidly approaching. CTNZ are pleased to have Professor Findlay speaking on a clinical trial perspective during the session 'fostering a culture of collaborative research between clinicians and laboratory scientists in New Zealand', and Dr Sanjeev Deva presenting results of '30 day mortality post systemic anti-cancer therapy in Auckland: a clinical audit' during the Eli Lilly Award oral presentation session. Jade Scott and Dr Vernon Harvey are presenting a poster presentation on behalf of the New Zealand SOLD investigators: "what is the optimal duration of trastuzumab therapy for breast cancer?"

Visit the conference website <http://www.conference.co.nz/index.cfm/nzso2010> for full program details and to register.

Clinical Trials Coordinator Meeting

This meeting is being held from 9am-5pm on Monday 3rd May and will be of interest to trial coordinators, research nurses and clinical research staff. Please note that the afternoon session is restricted to staff from regional cancer treatment centers and academic research groups. Further information, program and registration are available online at the conference website provided above.



Meeting Reports

Trans Tasman Radiation Oncology Group (TROG)

22nd Annual Scientific meeting 24-27 March, Queenstown



The ASM is the forum for first presentation of new trial ideas, and the meeting program was designed to facilitate discussion, assess scientific merit, determine multi-centre feasibility and provide recommendations regarding further development of a protocol. This was complemented by a number of practical workshops. Stephanie Pollard, Research Manager CTNZ, facilitated the Clinical Trial Management Workshop panel discussion on trial accrual and trial resources, from which a lot of great suggestions were made which TROG will take forward. This workshop also included educational sessions on Quality of Life, Resource Management, Practical skills for Radiotherapy Quality Assurance submissions and a GCP training session. Stephanie also presented on the topic 'GCP: whose role is it anyway?' which aimed at highlighting where GCP fits into the Australasian environment and defining some of the Investigator's responsibilities in this. Over 200 delegates attended the meeting. Congratulations to the meeting convenors Scott Babington and Maria Pearse as well as the organising committee for hosting the most successful and interesting meeting which served the needs of various disciplines.

Cochrane Collaboration Evidence on Trial Symposium Day

This year the NZ branch of the Australasian Cochrane Collaboration held a symposium day "Evidence on trial, has it made an impact on health" on 22nd March in Auckland. The meeting covered a range of important topics relating to clinical research. These included reliability, methodology for non-RCTs, patient perception, conflict of interest, global information needs, and strategies for changing practice. There were a series of excellent speakers from Australia, Canada, Denmark, India, Italy, New Zealand, UK, and USA.



The Cochrane Collaboration is an international, independent, not-for-profit organisation of over 27,000 contributors in more than 100 countries who work together to produce systematic assessments of healthcare interventions that are published online at the Cochrane Library, which all New Zealanders have free access to at www.thecochranelibrary.com. Some of the key contributors and reviewers are based in New Zealand

CASA404A2105 - Liver Impairment Study

Wellington has now opened to recruitment and have treated their first patient on this study. Auckland has also treated their first patient with moderate liver impairment, bringing the national total to 5 patients. International sites in Europe are still in the process of opening. The sponsor is currently working on a protocol amendment, which will hopefully allow extended access to ASA404 for patients on the study once protocol treatment (6 cycles) are completed.

ReCharge

ReCharge has extended the eligibility criteria to include patients with early stage disease requiring adjuvant chemotherapy. Patients about to start a 2 or 3 weekly regimen containing capecitabine, docetaxel, paclitaxel, 5FU or irinotecan (but not oxaliplatin) should be considered for ReCharge.

Currently there are 43 (target 200) patients enrolled in the trial, which is open for recruitment at Auckland, Tauranga, Palmerston North, Wellington Christchurch, Dunedin and Invercargill. Auckland is the highest recruiting site, with 19 patients so far. We hope to have Waikato Hospital open by the end of April. CTNZ will be holding a database lock on 5th May 2010 to prepare the interim report for ReCharge. The Data Monitoring Committee will meet in the first week of July to review safety of the trial.

SIRFLOX

Congratulations to Palmerston North for recruiting their first patient to the Sirflox trial! Dunedin and Christchurch are again excelling, with 11 and 10 patients recruited respectively.

A protocol amendment is awaited from the Sponsor which will allow the addition of Avastin to study treatment (mainly applicable in Australia) and capecitabine treatment post oxaliplatin relapse/toxicity. This will be submitted to ethics and distributed after receiving approval.

SOLD

Forty-one patients have now been randomised into this study, with 31 of these patients from Auckland. International recruitment is at 591, with Belgium and Iceland having recently joined the study. Original CRFs have been requested by Finland and New Zealand sites are in the process of collating these.

HRC Lung Cancer Study

Identification of barriers to the early diagnosis and management of people with lung cancer in primary care and description of best practice solutions

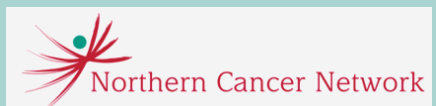
This 3 year HRC-DHBNZ funded study began in June 2009 with a literature review. The research phase commenced in January 2010 with a retrospective audit to document the clinical pathway from initial presentation to healthcare services until the first specialist assessment of ADHB, CMDHB and LDHB patients with a diagnosis of lung cancer in 2008 who were registered with one of the participating PHOs.

In May 2010, the following will commence: a national stock take to identify innovative services that could be of benefit to people with suspected lung cancer; patient interviews in Auckland and Lakes regions of people with a suspected or confirmed diagnosis of lung cancer in 2010 who either do not attend an appointment arranged by a GP or initially present to secondary care via ED; and GP feedback on the barriers from a GP perspective, via surveys and focus groups.

Further information on the study can be obtained at www.northerncancernetwork.org.nz (click on 'Research').



Principal Investigator Dr Wendy Stevens, Northern DHB Support Agency.



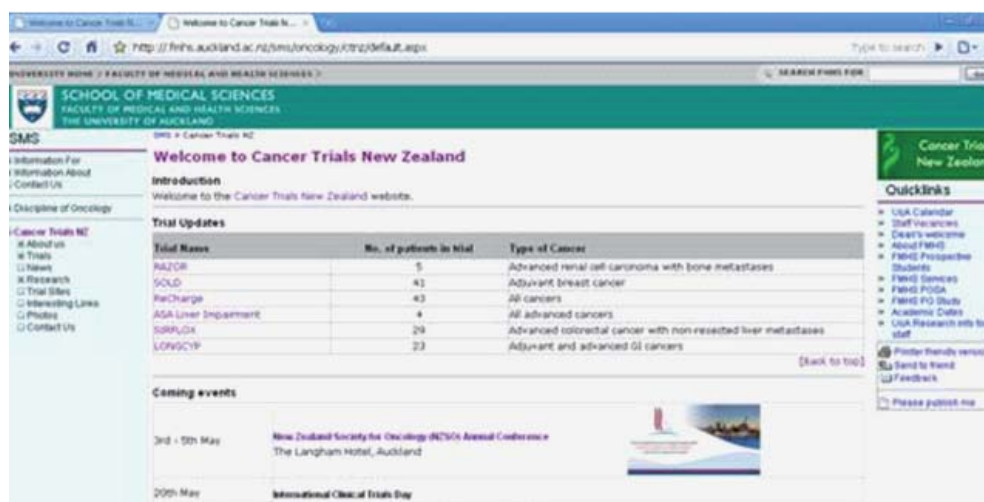
The CTNZ website has a new format - check it out at:

<http://www.fmhs.auckland.ac.nz/sms/oncology/ctnz/default.aspx>

The website is updated every 2 weeks. Please feel free to contribute any interesting articles, vacancies, meetings, training courses etc.

Currently on the website:

- CTNZ Trial Accrual
- Coming Events: NZSO, NZAcres
- News:
 - *NZ Ethics clarification on SAE reporting
 - *Cancer Consumer Representative Training Course
 - *PG Diploma in Clinical Research at Victoria University



CTNZ Staff Profile: Steve Duffey

Steve Duffey moved to New Zealand from the UK in March 2005. He had a research role in the Oncology and Haematology Pharmacy at Guy's Hospital in London before being employed as the Clinical Trial Co-ordinator at Auckland City Hospital Pharmacy. He joined CTNZ in January 2010 and we are enjoying his wealth of pharmacy knowledge and amicable personality.

Steve recently became a dad. His little son James is 5 and a half months old. When time allows he enjoys playing soccer.



Meetings 2010 Calendar

Visit our website: www.fmhs.auckland.ac.nz/sms/oncology

Happy Birthday...

Congratulations from the team at CTNZ to Professor Findlay on celebrating an important birthday this month!



Contact: Kasturi Naicker
Discipline of Oncology, Faculty of Medical & Health Sciences, The University of Auckland, Private Bag 92019, Auckland, 1142
Direct dial: +64 9 923 4927
Fax: +64 9 373 7927
Email: k.naicker@auckland.ac.nz
<http://www.fmhs.auckland.ac.nz/sms/oncology>

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