CTNZ Newsletter

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News about our magnesium study – MagLev

Having shown that the MagLev Study was feasible in terms of the measures used and participant acceptability, the trial team, led again by Dr David Porter, have recently submitted an application to Breast Cancer Foundation New Zealand in the hope of securing funding to extend the number of participants in the original MagLev feasibility Study to 80. This will allow us to look at the treatment effect on cognitive function in this group of women, which we were not powered to do in the feasibility phase.

We are calling this the MagLev B Study and we will hear the outcome of the application at the end of May.

CTNZ hosts a visit from the EDGE (UK) team

Earlier this month CTNZ hosted the second visit from the team at the Clinical Informatics Research Unit (University of Southampton, UK). As part of this visit they gave three demonstrations of the EDGE clinical research management system to a variety of different groups within the University, UniServices, Auckland DHB and Bay of Plenty DHB. EDGE was developed within the UK's National Cancer Research Network and is now used very widely in the UK both in hospitals (>80% of NHS Trusts) and academic institutions, no longer just in the area of cancer research. It is also used by a number of networks and academic units in Canada and shortly in South Africa.

CTNZ will be looking at this system further and will consider adopting it from a sponsor management perspective, with the hope that DHBs may adopt it in the future for a more collaborative and streamlined approach to clinical research in NZ

New electronic data capture software in action

In our December issue CTNZ announced the new electronic data capture (EDC) software that we have bought, ALEA, which is fully GCP compliant. Our Data Managers, Trial Managers and Monitors received training from the developers FormsVision before Christmas. All our databases will now be built in the ALEA system. The KISS Study is already live and being used by the open sites, THYmine2 and PROSPER are currently being built.

CURRENT TRIALS and STUDIES

KISS

Four sites are now open for the KISS Study, Christchurch was opened in January and Middlemore (Counties Manuaku) in February. Christchurch have already recruited their first participant and total recruitment is standing at three participants.

Dunedin	1
Christchurch	1
Auckland	1
Counties Manukau	0
TOTAL	3

Palmerston North Hospital and Wellington Hospital are being set up and will receive their site initiation visits in April and May. The database for the study is working well ad we are looking forward to the first monitoring visit which will occur as soon as a site has recruited their second patient.

The Bone Sub-study has received provisional approval from HDEC subject to some changes that are now being considered by the committee. This sub-study is only being done at Auckland and Middlemore, we hope to open it at these sites in mid-late April. For further information, please contact Lindsey: **l.wylde@auckland.ac.nz**

MagLev

The plan for MagLev is to extend the current sample to 80 participants, this will require an additional 46 patients and additional funding (see front page for more details) For more information please contact Sarah: **s.benge@auckland.ac.nz**

SOLD

Tumour tissue sample collection is currently underway at sites. Patients continue to be followed by annually. For further information, please contact Jade: **j.scott@auckland.ac.nz**

THYmine 2

The THYmine 2 study has recruited 8 patients since it began at end of November 2017. Recruitment has been slower than anticipated due to the holiday period and a few logistical issues. The latter have been addressed and we are expecting recruitment to increase on a weekly basis. We are aiming to recruit 200 patients over a 26 month period through the Auckland Regional Cancer and Blood Centre. Potentially eligible participants are those with gastrointestinal or metastatic breast cancer who are planned to receive a chemotherapy schedule containing fluoropyrimidine (Capecitibine or 5-FU) as a monotherapy or in combination. For further information about the THYmine2 Study, please contact Rebecca: **r.hu@auckland.ac.nz**

MELVAC

We have completed recruitment for this study, with 3 participants still in the middle of their study visits and the last 2 participants awaiting randomisation. So far, 27 participants have completed the study. All vaccinations have gone smoothly to date. The team is currently preparing the 6 monthly DMC report for the next meeting in April. For further information about MELVAC, please contact Rebecca: **r.hu@auckland.ac.nz**

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. For further information, please contact Michelle : **MiWilson@adhb.govt.nz**

JOB VACANCY

We are advertising for a new Clinical Trials Manager, if you are interested or you know anyone that may be, please click **here** to find the role description and apply via the University portal

CTNZ will be closed from

*5**pm on Thursday 29st March** and will reopen at **9am on Wednesday 4th April.***

Trial specific contacts over this period are:

Trial	SAE Reporting	Urgent Queries
SOLD	Fax directly to Finland: **00 358 947 173 181**	Dr Michael Findlay **021 753 735**
MELVAC	Email: ctnztrialservices@auckland.ac.nz and phone 09 923 4927 (leave a message)	Dr Catherine Barrow **027 703 9952** Dr Michael Findlay **021 753 735**
KISS	Email: ctnztrialservices@auckland.ac.nz and phone 09 923 4927 (leave a message)	Dr Peter Browett **021 473 817**
THYmine2	No SAE reporting required	Dr Michael Findlay **021 753 735**

Cancer Society
Te Kāhui Matepukupuku o Aotearoa

With thanks to the Cancer Society Auckland and Northland

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