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AUSTRALASIAN
**KIDNEY
TRIALS
NETWORK**

AUSTRALASIAN KIDNEY TRIALS NETWORK

BLOCADE Newsletter

Seasons Greeting from the BLOCADE Study



Dear BLOCADE Collaborators,

Welcome to the inaugural "BLOCADE Newsletter". It provides an opportunity to update you about the BLOCADE Study and to thank you all for your hard work on BLOCADE.

Since the first participant was recruited in May, 32 participants have commenced, or will soon commence, the Run-in phase.

This is largely thanks to a stellar recruiting effort from Auckland Hospital. Screening and recruiting has been hard work to date and some sites have screened most of their prevalent patients and are now relying on screening patients as they commence dialysis. We are learning from this experience and the screening logs are an important source of information.

We hope to have 12 sites actively recruiting by early 2012 and to complete recruiting by the end of 2012 requires each site to recruit one patient per month. I say this to give an idea of the scale of the task and to encourage everyone to persist with screening and recruiting for BLOCADE over the next 12 months.

I appreciate that we are coming into a holiday season where there may be other priorities, but would urge those who are working through this time to keep recruiting for BLOCADE in mind.

The other priorities are important so I would also urge you to have a happy and safe Christmas!

Matthew

PS: I will be available by email or telephone to answer any questions regarding BLOCADE over the Christmas and New Year period, but will be away from January 16-20, and Liza will be back on board by this time.



The
BLOCADE
trial

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Recruitment Update

Out of 12 sites, 7 are actively recruiting. Currently we have 32 participants in the trial (excluded are 6 screen failures) which is 21% of the total recruitment target of 150.

To date we have:

- 38 participants who consented
- 32 participants in the trial (excluding screen failures)
- 28 participants commenced Run-in
- 18 participants were randomised
- 6 were considered *Screen failures* (withdrawal prior Run-in phase)
- 7 withdrawals in the study (failed Run-in phase)

Congratulations to the following sites for recruiting the most number of participants: Auckland City Hospital (13 participants), followed by Austin Health, Middlemore Hospital and Royal Melbourne Hospital with 5 participants each.

We welcome 3 additional new sites to the study —John Hunter Hospital, Royal North Shore Hospital and Eastern Health who have or will start with ethics applications .



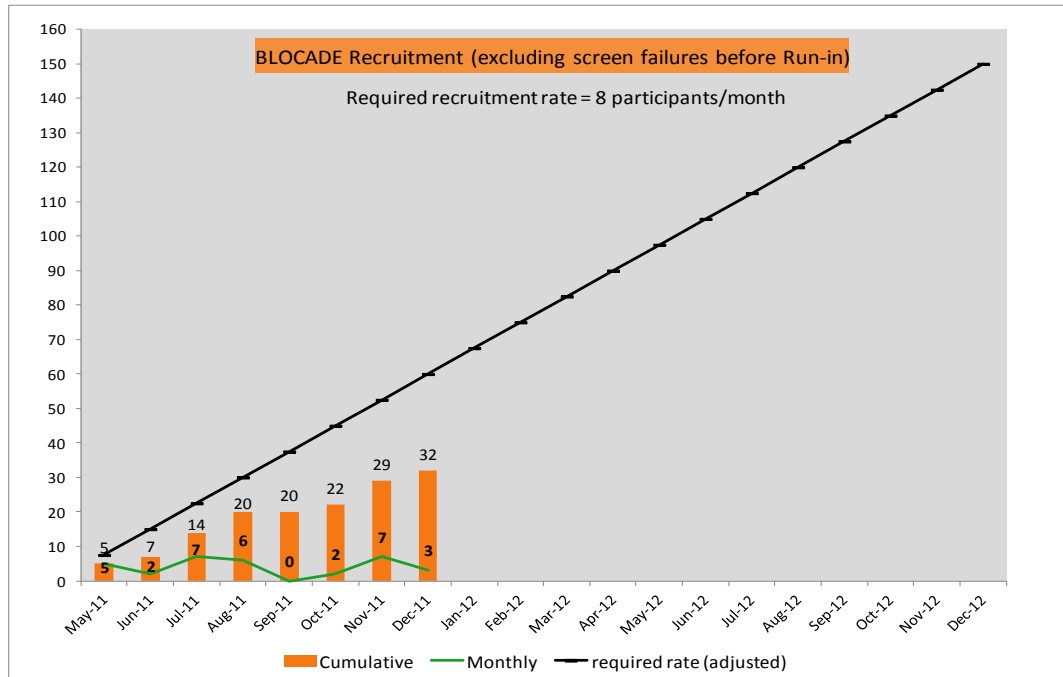
Congratulations to Robert Carroll and Eileen Scott from the Royal Adelaide Hospital (CNARTS) for consenting the 1st participant for BLOCADE on the 16th of May 2011.



BLOCADE – recruitment status as of 19th of December 2011

Sites	Status	Screen failures (withdrawn prior Run-in)	Number of Participants in the trial	Randomised	Withdrawn from trial
Auckland City Hospital	Active	1	13	9	2
Austin Health	Active	3	5	3	
Dunedin Hospital	Active	1	0		
Eastern Health	Just joined		-		
John Hunter Hospital	Just joined		-		
Middlemore Hospital	Active		5	3	2
Princess Alexandra Hospital	Active		1		
Royal Adelaide Hospital	Active	1	3	1	1
Royal Melbourne Hospital	Active		5	2	2
Royal North Shore Hospital	Just joined		-		
Royal Prince Alfred Hospital	Active		0		
Westmead Hospital	Not ready		-		
Total: 12 sites		6	32	18	7

cont. Recruitment Update



Recruitment Reminder



Monitoring Updates

A total of 3 sites have now had at least one monitoring visit; Royal Adelaide Hospital (CNARTS), Austin Health and Royal Melbourne Hospital, have all been visited this year. Other sites will be monitored next year.

From these visits, the following have come to light as important issues to consider whilst recording data for the trial.

- **Illegible data** - please make sure that numbers and letters are clearly written and are legible.
- **Corrections not properly recorded** - mistakes corrected using white-out or scratched out were observed on the paper CRFs. The right way to correct mistakes is to cross out the mistake with a single line (so the original value is visible) and initial and date the correction.
- **Incomplete CRFs** - data are not current. All paper CRFs must be completed at each study visit if possible or at least 2 weeks if waiting for lab results and other tests.

Monitoring visits are important not only for source data verification but it also provides a unique opportunity to ask Liza about the trial one-on-one with any questions and concerns you have.

FAQs

Q: Why do we have to make note of which troponin assay was used and the reference range in the baseline CRF?

A: Different hospitals use different troponin assays. Assays differ in what level of troponin they detect, in performance, and in the cut-off value that the laboratory reports for clinicians to base decisions upon.

The purpose of the baseline troponin is to have a level to assist clinicians when participants subsequently present with acute coronary syndromes. This will also assist our Endpoint Adjudication Committee. It is therefore essential to know the assay and its reference range in order to interpret results from different laboratories.

Please be aware that hospital laboratories may change the assay that they are using during the course of BLOCADE. For example, Austin Health will replace the Beckman Coulter troponin I assay with the Roche high-sensitivity troponin T assay this January. This will have a different reference range and in patients on dialysis, will have implications for the number of patients with levels above the reference range.

For the purposes of subgroup analysis in the study, troponin will be measured on stored serum using the same assay.

Q: What should we do if the troponin is abnormal?

A: Although abnormal cardiac troponin is very common in patients undergoing dialysis, the optimal clinical management of such abnormalities is not known. The potential subgroup analysis above may help to answer this question. It is known that a single, or serial, abnormal cardiac troponin is associated with a 2-3 fold increased risk of death compared to patients with troponin below the cut-off. Because it was anticipated that patients with abnormal troponin would be identified through participation in BLOCADE, the Operations Manual (p38) recommends contacting participants with abnormal troponin to see if they have unreported cardiac symptoms. Investigation and management is then at the discretion of the Site PI, because there is insufficient evidence to recommend a specific management plan.

Publications related to BLOCADE

Badve SV, Roberts MA, Hawley CM, Cass A, Garg AX, Krum H, Tonkin A, Perkovic V. Effects of beta-adrenergic antagonists in patients with chronic kidney disease. *JACC*. 2011 Vol 58 (11) 1152-61.

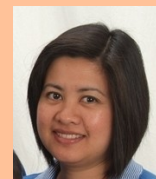
This article was reported on by "The Doctor's Channel.com" in September 2011 as "Badve SV. Beta-blockers benefit chronic kidney disease patients with heart failure".

A review of blood pressure measurement has just been submitted.

Blood pressure measurement is important!



For Further
Information :



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