



Newsletter: August 2014

SOLID Website: www.solid.org.nz

Dear all,

This newsletter provides you with an update of recent progress since the last edition in May. The statistics recorded here current up to 30th July 2014.

Regarding recruitment, although there was only a small increase in the actual registered numbers (85 participants compared to 79 in May), 11 registered participants had been randomised since last edition. This boosted the randomisation number to 73. This is a result of good effort in conducting efficient baseline assessments to convert participants from registration to randomisation. In fact, the randomisation number is the one that counts and with our new target of 96 randomised, obviously, there is still a gap to be filled.

Counties Manukau DHB and its self-care unit, in combination, have reached 42 registered participants. There are some more patients who have agreed to participate and will be registered once they complete their home training.

Waikato DHB and self-care unit, which started in late 2013, are still working on further recruitments, and they have done well to reach the midpoint of a combined target of 10-15.

Both CCDHB and CDHB are close to, or have reached their targeted registered number. However, 5 are still undergoing baseline assessments and have not yet been randomised. We have also asked both sites to continue with recruitment of another 2-3 more each.

The focuses of WDHB and ADHB have now been shifted more towards their associated self-care units. Waitakere self-care unit has registered 3 participants, among which 2 of them are about to complete their baseline assessments before randomisation. Greenlane self-care unit is all set to go. We are pleased to have Mary He and Jerred George on board as coordinators for this site and they are about to start recruiting their first participant this month.

The process of involving Southern DHB is also on going.

In order to get a significant result for this extraordinary trial, we all need to continue on our effort to achieve targeted numbers. As well as getting patients signed up for SOLID, we also need to convert the registered participants into randomisation. If we are able to complete all participants undergoing baseline assessments in a timely manner, it will have a huge boost to the randomisation number.

To site investigators, one of our trial competitors, "Volume, Sodium and Blood Pressure Management in HD (VSBP)" conducted by Rajiv Saran in University of Michigan, is progressing along and is expected to finish recruitment within the next couple of months. Although the trial uses different low dialysate sodium concentration (137 mmol/L) and uses only blood pressure as the end point, it has put some pressure on us. Therefore, your ongoing effort is still required to make this work and it will be very much appreciated. We understand that this is a very involved and demanding trial. Therefore, please let us know if there is any specific support that we can provide to help you achieve these goals.

To site coordinators, it is very important to send all the required documentation (eg CRFs, screening logs, and chip cards) to Brenda and me in a timely manner for data entry and recording purposes. We will also appreciate the accuracy of your recordings (eg Sphyg, BCM, and CRFs) which will minimise the chance of error and the chance that we have to contact you for further clarification. Please feel free to give us a call or an e-mail if you encountered any technical difficulties, or needed clarification.

The next DMC meeting will be conducted in October 2014. They have requested that we provide information on those participants who do not routinely record their intra-dialytic blood pressures. This information will help to explain why we have so much missing data on intra-dialytic hypotension (IDH) as a safety endpoint of the trial. If you have not already done so, could you please send Brenda a list of these participants and their reason for not recording intradialytic BP's.

We are pleased to announce that Mac SOLID study protocol has been published last month in BMC Nephrology as "Rationale and design of the myocardial microinjury and cardiac remodelling extension study in the sodium lowering in dialysate trial (Mac-SoLID study)" (BMC Nephrology 2014, 15:120 doi:10.1186/1471-2369-15-120) for your reference.

Lastly, we have received some very positive feedbacks from our participants upon being given their Countdown gift cards at the completion of the trial. It has been a lovely way to show our appreciation for all the time and effort they have put into the trial.

Regards,

Daniel Lin, Brenda Luey, and Mark Marshall

CCRep details

| Role | Name | Phone | Email |
|-----------------|------------------|--------------|-------------------------------|
| Project Manager | Kathryn Askelund | 021 890 593 | kathryn.askelund@ccrep.org.nz |
| Research Fellow | Daniel Lin | 021 783 039 | daniel.lin@middlemore.co.nz |
| Research Nurse | Brenda Luey | 021 824 982 | brenda.luey@ccrep.org.nz |

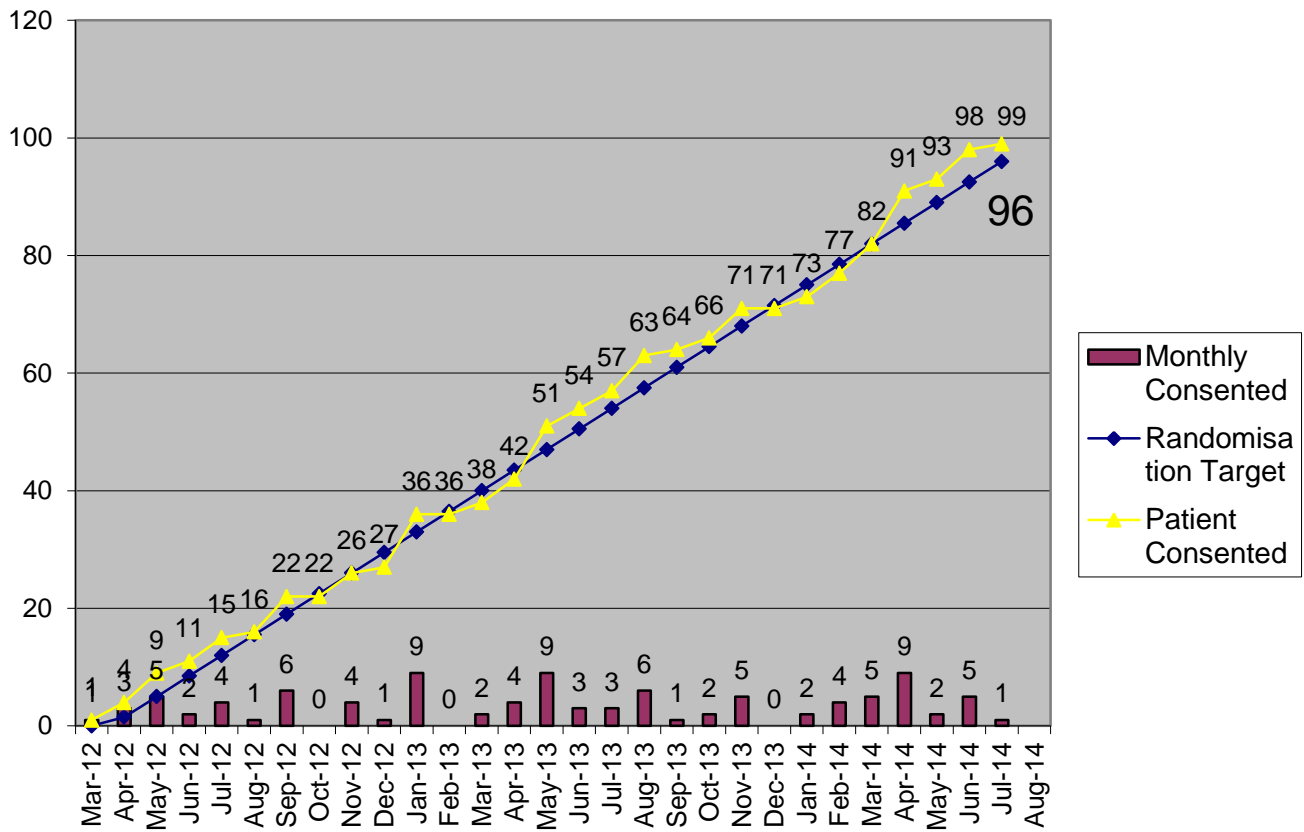
Site details

| Site | Investigator | Contact no. | Coordinator | Contact no. |
|----------------------------------|------------------------|--------------------|-----------------------|--------------------|
| CMDHB and Self Care | Mark Marshall (PI) | 021 461 766 | Brenda Luey | 021 824 982 |
| | Jo Dunlop | 021 575 251 | | |
| ADHB | David Semple | 021 415 458 | Grace Muyoma | 021 244 5606 |
| WDHB | Janak De Zoysa | 021 779 224 | Grace Muyoma | 021 494 395 |
| CCDHB | Philip Matheson | 027 495 9702 | Tess Ostapowicz | 04 806 0535 |
| CDHB | David McGregor | 03 364 0655 | Jenny Usher | 03 364 0197 |
| | John Irvine | | | |
| Waikato DHB and Self-Care | Kannaiyan Rabindranath | 021 494313 | Deborah Peek | 021 759 443 |
| Waitamata Self-Care | Janak De Zoysa | 021 779 224 | Erin Baker | 021 204 3007 |
| Greenlane Self-Care | David Semple | 021 415 458 | Mary He Jerred George | TBC |
| SDHB | John Schollum | | TBC | |

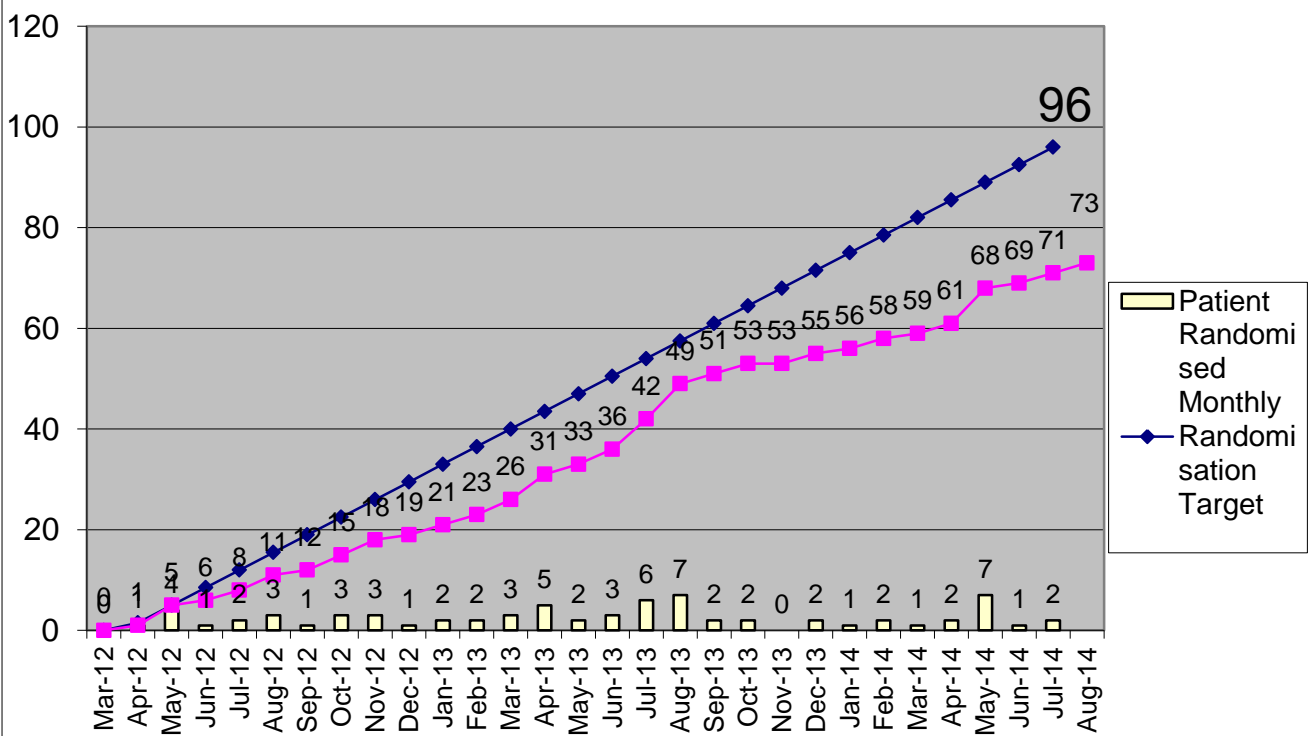
Statistics up to 31 July 2014

| Sites | Target of Randomised Patients | Total Registered | Withdrawal before randomisation | Actual Registered | Randomised | Baseline in progress | Withdrawal or study treatment cessation after randomisation | |
|---------------------------------|-------------------------------|------------------|---------------------------------|-------------------|------------|----------------------|---|----------|
| | | | | | | | | Deceased |
| Counties Manukau DHB | 46 | 43 | 6 | 37 | 35 | 2 | 6 | 1 |
| Auckland DHB | +GLH self-care =13 | 8 | 3 | 5 | 4 | 1 | 1 | |
| Waitemata DHB | + self-care unit =13 | 10 | 3 | 7 | 6 | 1 | | |
| Capital and Coast DHB | 15-16 | 15 | | 15 | 11 | 4 | 2 | 1 |
| Canterbury DHB | 5-10 | 8 | 1 | 7 | 6 | 1 | 2 | |
| Waikato DHB | 10 | 7 | 1 | 6 | 5 | 1 | | |
| Counties Manukau Self-care unit | 10 | 5 | | 5 | 4 | 1 | | 1 |
| Waitakere Self-care unit | + WDHB = 13 | 3 | | 3 | 2 | 1 | | |
| Waikato DHB Self-care Unit | 4-5 | | | | | | | |
| Greenlane Self care unit | +ADHB self-care =13 | | | | | | | |
| Southern DHB | 6 | | | | | | | |
| Total | Target 96 | 99 | 14 | 85 | 73 | 12 | 11 | 3 |

SOLID Recruitment Summary (Consented vs Target)



SOLID Recruitment Summary (Randomised vs Target)



| CMDHB (1) | Number of Participants in the study (excluding screen failures) | Target recruitment number | Participant study number and initials | Date enrolled | Stage at which the participant has completed (eg titration, follow up) | Has the participant withdrawn? (stage they were on and reason) |
|-----------|---|---------------------------|---------------------------------------|---------------------|--|---|
| | 37 | 46 | 11001 | 26/03/2012 | F12. completed | |
| | | | 11002 | 16/04/2012 | End –Runout 4 | |
| | | | 11003 | 20/04/2012 | End | WD after T3.Renal Tx. For f/up |
| | | | 11004 | 27/04/2012 | F12 .completed | |
| | | | 11006 | 08/05/2012 | End –Runout 3. | |
| | | | 11007 | 14/05/2012 | withdrawn | WD at baseline. Non-compliance. |
| | | | 19008 | 21/05/2012 | F12 .completed | |
| | | | 11010 | 13/06/2012 | F12. completed | |
| | | | 11011 | 14/06/2012 | End. | WD after T3. A/E. SAH.Now on CAPD. For f/up |
| | | | 11013 | 06/07/2012 | End- Runout 4 | |
| | | | 11017 | 07/09/2012 | Baseline incomplete | On hold for 8/12 at baseline as pt too busy, then WD as pt now on CAPD (7/5/13) |
| | | | 11018 | 10/09/2012 | Withdrawn | WD at baseline. Non-compliance. For Transplant. |
| | | | 11019 | 11/9/2012 | Withdrawn | WD after T2 hypotension. Final cessation 12/7/13. |
| | | | 19024 | 12/11/2012 | F12. Completed | |
| | | | 11026 | 30/11/2012 | End. Runout 3 | |
| | | | 19030 | 25/01/2013 | End. Runout 1 | 10/2/14: To Waikato at End |
| | | | 11032 | 30/01/2013 | Completed. | WD 22/5/13 (after F3) but for follow-up. Retitration (started 8/5/13) from rando 135mM up to 140 due to cramps. |
| | | | 11033 | 29/01/2013 | End. Runout 3 | |
| | | | 11034 | 30/01/13 | Withdrawn | 21/6/13. WD before F3. Deceased. |
| | | | 11035 | 30/01/13 | F12 in progress | |
| | | | 11036 | 29/01/13 | Completed | 26/3/14: transfer to ADHB. To finish F12 there |
| | | | 11037 | 13/03/13 | End. Runout 2 | |
| | | | 11038 | 25/03/13 | End. Completed | |
| | | | 11039 | 5/04/13 | End. Runout 3 | |
| | | | 11046 | 10/05/13 | Completed.? For runouts | |
| | | | 11047 | 13/05/13 | F12 in progress | |
| | | | 11049 | 14/05/13 | Completed | |
| | | | 11051 | 23/05/12 | F12 in progress | 19/9/13 WD due to ongoing cramps and headaches. Back to 138mM. For f/up |
| | | | 11054 | 24/06/13 | Baseline on hold | 25/7/13 screen failure. Await wt loss for MRI. |
| | | | 11057 | 24/7/13 | F12 in progress | |
| | | | 11058 | 1/8/13 | F6 .WD | 20/3/14: WD. Low BP's. No F/ups |
| | | | 19059 | 2/8/13 | F9 | |
| | 11062 | 2/8/13 | F6 | Transfer to Waikato | | |
| | 11063 | 2/8/13 | F9 | | | |

| | | | | | | |
|-----------|-----|----|-------|------------|----------------------|---|
| | | | 11064 | 4/9/13 | Reg | 30/9/13 WD.could not give time to the study |
| | | | 11065 | 4/10/13 | F6 | |
| | | | 11070 | 4/11/13 | F6 | 21/2/14: WD due to cramps,tired,headache on 135. Back to 138mM. For follow up |
| | | | 11075 | 7/2/13 | T1 | |
| | | | 11077 | 19/2/14 | Reg | Onhold.Claustrophobic. For trial MRI |
| | | | 11085 | 2/4/14 | T 3 | |
| | | | 11091 | 14/4/14 | Baseline in progress | 30/4/14: WD as increased dialysis to 4x/week |
| | | | 11092 | 9/5/14 | Rando | |
| | | | 11093 | 30/5/14 | Baseline in progress | |
| ADHB (2) | 4-5 | 13 | 29021 | 19/09/2012 | F12 | |
| | | | 29022 | 25/09/2012 | F12 | 16/6/13: WD. Kidney Tx. |
| | | | 21025 | 23/11/2012 | F12 | |
| | | | 21043 | 06/05/13 | F9 | |
| | | | 21061 | 7/8/13 | Reg | WD consent |
| | | | 21071 | 5/11/13 | BA | WD. Claustrophobic. Could not tolerate MRI. |
| | | | 29072 | 8/1/14 | Reg | WD. Moving to Rotorua |
| | | | 29087 | 2/4/14 | Reg | Social issues. ?to WD |
| WDHB (3) | 6 | 13 | 31012 | 06/07/2012 | F12. Completed | |
| | | | 31014 | 10/07/2012 | BA | WD before randomisation |
| | | | 31027 | 06/12/2012 | F9. | |
| | | | 31028 | 09/01/2013 | BR | WD before randomisation. Fistula problems |
| | | | 31029 | 23/01/2013 | F6 | WD |
| | | | 39031 | 23/01/2013 | BR - withdrawn | Withdrawn before randomisation social issues. Dialysing in-centre. |
| | | | 39044 | 08/05/2013 | F9 | |
| | | | 39060 | 07/08/13 | BR | WD |
| | | | 31073 | 8/1/14 | T5 | |
| | | | 39084 | 2/4/14 | Rando | |
| CCDHB (4) | 15 | 24 | 49005 | 01/05/2012 | End. Completed | 25/2/13: WD.Renal Transplant. Has agreed to follow-up. |
| | | | 49009 | 30/05/2012 | End. Completed | |
| | | | 41016 | 15/08/2012 | End. completed | 12/3/13:WD.Kidney Tx |
| | | | 41023 | 07/11/2012 | F9. withdrawn | 2/2/14: WD.Deceased |
| | | | 41040 | 10/4/2013 | F12 | |
| | | | 41041 | 17/4/2013 | F12 | |
| | | | 41042 | 17/04/2013 | F12 | |
| | | | 41048 | 15/05/13 | F9 | |
| | | | 41055 | 05/07/13 | Reg | On hold |
| | | | 41066 | 17/10/13 | F6 | |
| | | | 41074 | 1/2/14 | Titration | |
| | | | 41088 | 2/4/14 | Titration | |
| | | | 41090 | 4/4/14 | Reg | On hold till July |
| | | | 41094 | 6/6/14 | Baseline | |

| | | | | | | |
|----------------------------------|---|-----|-------|------------|-------------------------|---|
| | | | 41097 | 14/6/14 | Reg | |
| CDHB (5) | 7 | 5 | 51015 | 19/07/2012 | F3 withdrawn | WD.F3.10/1/13 Dysphasia,confusion, Septicaemia. Pt not keen on f/up. to try again later. |
| | | | 51020 | 19/09/2012 | F12. Completed | |
| | | | 59045 | 09/05/2013 | F12 | |
| | | | 59050 | 22/05/2013 | F12 Due 18/6/14 | |
| | | | 51052 | 05/06/13 | F12 Due 11/6/14 | |
| | | | 51053 | 24/06/13 | F6. withdrawn | 5/2/14:WD. Moving out of area |
| | | | 51056 | 08/07/13 | Reg | 15/7/13. WD.unable to tolerate MRI |
| | | | 51086 | 2/4/14 | Reg | On hold as SAE during BA |
| Waikato (6) | 6 | 10 | 61067 | 1/11/13 | Randomised | |
| | | | 61068 | 1/11/13 | Reg | Withdrawn. Unable to complete MRI |
| | | | 61069 | 1/11/13 | Randomised | |
| | | | 11062 | | F3 | Transfer from CMDHB |
| | | | 61078 | 3/3/14 | Rando | |
| | | | 61079 | 4/3/14 | Rando | |
| | | | 61082 | 28/3/14 | Rando | |
| | | | 61089 | 3/4/14 | Reg | |
| MSC satellite (7) | 5 | 10 | 71076 | 07/02/14 | F3 | 27/7/14: deceased |
| | | | 71080 | 10/03/14 | F3 | |
| | | | 71081 | 12/3/14 | T4 | |
| | | | 71083 | 1/4/14 | T3 | |
| | | | 71096 | 12/6/14 | Baseline in progress | |
| | | | | | | |
| Waitem ata selfcare (8) | 3 | 4-5 | 81095 | 10/6/14 | Rando | |
| | | | 81098 | 24/6/14 | Rando | |
| | | | 81099 | 29/7/14 | Reg | |