

AFFINITY TRIAL NEWSLETTER

AFFINITY Trial Coordinating Centre:

Email: affinity@health.wa.gov.au

Phone: (08) 6151 1061 Fax: (08) 6151 1028

Website: www.affinitytrial.org

ISSUE: 6 10th June 2016



242

Participants Randomised.



GOAL: To randomise 1600 participants by the end of 2017.

WHAT'S THE LATEST



PROTOCOL AMENDMENT RECEIVES HREC APPROVAL

Investigator responsibilities

Randomisation, and 28-day and 90-day follow up (face-to-face, phone or post)

Reimbursement to the study investigators will be \$1000 per participant.

Please read the full update on pg. 2.

AFFINITY BM DNA/MRI SUB STUDY

DNA component: Analysis of DNA and other blood biomarkers of neurological recovery and response to therapy.

Site investigators will be paid Aus\$200.00 per participant.

MRI component: Consenting participants will undergo an additional MRI at baseline and another after completion of the 180 day follow up.

Site investigators will be paid Aus\$200.00 for each MRI scan.

Pathology and MRI costs will be covered as negotiated.

Please read the full update on pg. 3.

PROTOCOL AMENDMENT UPDATE

Since the last newsletter the proposed protocol amendment to the AFFINITY trial [protocol version 5] has received full HREC approval from all of the trials Lead HREC committees in WA, NSW, VIC, Olds, SA, ACT and New Zealand.

The key changes to the trial design and protocol are:

- Dispensing **six months'** supply of trial medication to the patient at randomisation (i.e. instead of two separate dispensations at baseline and 3 months)
- **No** mandatory blood tests at day 28 (hence day 28 follow up remains by the clinician, could be conducted by telephone, and is centred toward adherence to trial medication/adverse effects, tolerance of trial medication, and any secondary outcome measures such as depression, falls, stroke, seizures, etc)
- Following completion and submission of the Day 28 and **Day 90** follow up by the site the trial office sends a letter to the participant introducing the trial office and advising of importance of
 - adherence to trial medication until 6 months after randomisation,
 - future contact from the trial office by phone +/- questionnaire for follow-up at 6 and 12 months,
 - return of trial medication bottle after 6 month follow up, and
 - contact details in the event of any questions regarding the trial.
- **Centralising** follow up after the day 90 visit (ie at 6 and 12 months) by telephone +/- postal questionnaire by the AFFINITY trial office in Perth.
- Return of trial medication to the trial office after 6 months follow-up contact will be coordinated by trial office.

Hence, **investigator responsibilities** will be

1. Randomisation, and
2. 28-day and 90-day follow up (face-to-face, phone or post)

Reimbursement to the study investigators will be \$1000 per participant.

The AFFINITY trial office has been working with sites around the country to submit the amendment for local governance site approval. Once this approval is received sites will be transitioned to protocol version 5 on the AFFINITY web site. We trust these amendments will facilitate recruitment at your site.

AFFINITY BM DNA/MRI SUB STUDY

The Assessment of Fluoxetine in Stroke Recovery (AFFINITY) trial Blood and Imaging Biomarker Sub-study: AFFINITY-BM sub study

The AFFINITY-BM sub study aims to complement the main AFFINITY trial by providing additional information about **blood** factors (e.g. genomic, proteomic) and **imaging** factors (e.g. functional MRI) that may help refine prediction of functional recovery after stroke and response to fluoxetine.

Blood biomarker study

All patients who have consented to participate in the AFFINITY trial are subsequently asked if they may consent to providing a **single blood sample** for analysis of DNA and other blood biomarkers of neurological recovery and response to therapy.

The blood samples will be processed, frozen and stored locally for batch shipment to Pathwest laboratories at QE11 Medical centre in Perth when appropriate.

The costs of laboratory processing, storage (as negotiated) and frozen shipment to Perth will be borne by the AFFINITY trial.

Site investigators will be paid Aus\$200.00 upon arrival at Pathwest, Perth of stored blood samples from each consenting participant.

MRI biomarker study

Patients who have consented to participate in the AFFINITY trial are subsequently asked if they may consent to undergoing two MRI brain scans - at baseline (within 3 weeks of randomisation) and at 6 months follow-up - according to a standardised protocol, for analysis of structural and functional brain biomarkers of neurological recovery and response to therapy.

The costs of the MRI (as negotiated) will be borne by the AFFINITY trial.

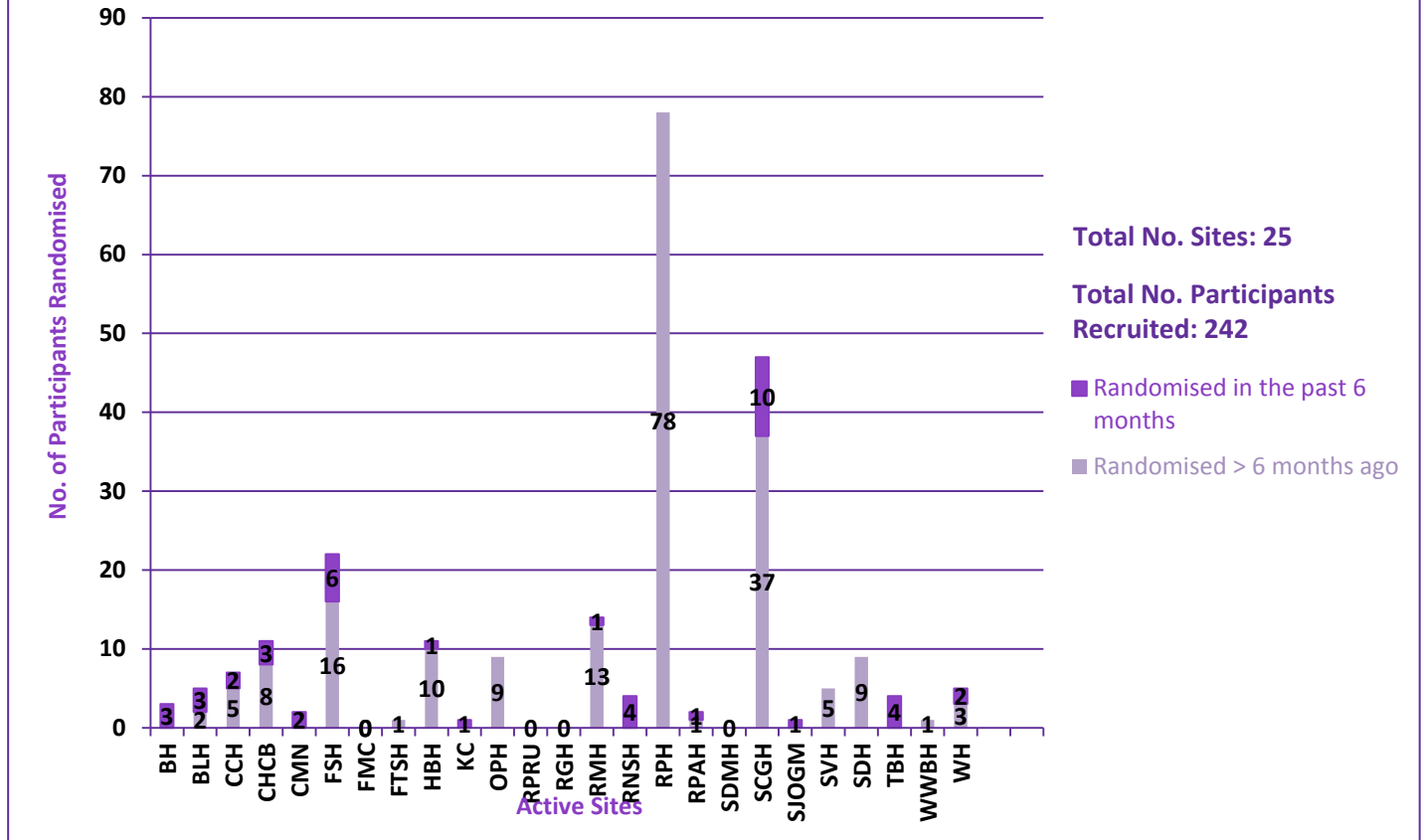
Site investigators will be paid Aus\$200.00 for the baseline MRI and \$200.00 for the follow-up MRI of each consenting participant.

Ethical approval has been granted for Western Australia and submission has been made to the lead HREC committee for NSW, VIC, QLD and SA and we are currently anticipating approval in the near future. Once this approval is in place the sub study will be submitted in the ACT and following that in New Zealand. Support will also be available to help site investigators with local governance applications should it be required.

If your site would like to participate in either or both of the blood and imaging sub studies? Email anne.claxton@health.wa.gov.au or phone (08) 6151 1058 or (08) 6151 1061

AFFINITY Recruitment

Updated: 10 June 2016



Site Abbreviation Key:

BH- Belmont Hospital (Dr Michael Pollack)

BLH-Blacktown Hospital (Prof Richard Lindley)

CCH-Campbelltown & Camden Hospitals (Dr Stanley Levy)

CHCB-Calvary Health Care Bruce (Dr Yash Gawarikar)

CMN-Calvary Mater Newcastle (Dr Elizabeth Pepper)

FSH-Fiona Stanley Hospital (Dr Darshan Ghia)

FMC-Flinders Medical Centre (Prof Andrew Lee)

FTSH-Footscray & The Sunshine Hospitals (A/Prof Tissa Wijeratne)

HBH-Hawke's Bay Hospital (Dr John Gommans)

KC - Kingston Centre (Dr Peter New)

OPH-Osborne Park Hospital (Dr Kapila Abeysuriya)

RPRU-Rankin Park Rehab Unit (Dr Michael Pollack)

RGH-Rockingham General Hospital (ON HOLD-no site PI)

RMH-Royal Melbourne Hospital (Prof Stephen Davis)

RNSH-Royal North Shore Hospital (A/Prof Martin Krause)

RPH-Royal Perth Hospital (ON HOLD - no site PI)

RPAH-Royal Prince Alfred Hospital (Prof Craig Anderson)

SDMH-Shoalhaven District Memorial Hospital (Dr Jeremy Christley)

SCGH-Sir Charles Gairdner Hospital (W/Prof Graeme Hankey; A/Prof David Blacker)

SJOGM - St John of God Midland (Dr Timothy Bates)

SVH-St Vincent's Hospital (A/Prof Romesh Markus)

SDH-Swan District Hospital (Dr Timothy Bates)

TBH-Taranaki Base Hospital (Dr Bhavesh Lallu)

WWBH-Wagga Wagga Base Hospital (Dr Martin Jude)

WH-Wellington Hospital (Dr Harry McNaughton)

Active centres since last newsletter



We welcome Dr Peter New (Kingston Centre), Dr Tim Bates (St John of God Midland) and Dr Jeremy Christley (Shoalhaven District Memorial Hospital) and their respective teams to the AFFINITY Trial collaboration. All three sites are now open for recruitment.

Congratulations - First Patient Randomised

Congratulations to Dr Peter New (KC), Tim Bates (SJOGM), Dr Michael Pollack (BH), Dr Elizabeth Pepper (CMN), Dr Martin Krause (RNSH), Dr Bhavesh Lallu (TBH) & their teams for randomising their first patient to the AFFINITY Trial.

Campbelltown and Camden Hospitals

Camden and Campbelltown Hospital is a 327 bed acute care facility under a single governance structure which deliver quality healthcare to residents in the Macarthur region in South West Sydney. The catchment area is estimated at close to 280,000.

Macarthur was the birthplace of Australia's wool, wine and wheat industries and is rich in history and character.

The acute stroke unit was established at Campbelltown Hospital in 2005 and we work in close collaboration with our Camden colleagues who are well known for excellence in both inpatient and outpatient stroke rehabilitation services.

We have participated in investigator lead, multi-site studies including stroke thrombolysis studies.

Our team find that participation in the AFFINITY trial is a great way to further support and encourage some of the wonderful people that we meet during their first year journey of stroke recovery.



Here are some of our team members.

From left: Dr Ho Choong (neurologist), Bev Macdonald (stroke liaison nurse), Prof Stan Levy (neurologist), Dr Louise Rigney (neurologist) and Dr Sumana Gopinath (neurologist)



DID YOU KNOW?

We actually do not see with our eyes - we see with our brains. The eyes are basically the cameras of the brain. One-quarter of the brain is used to control the eyes.



ASIA PACIFIC STROKE CONFERENCE
combined with Stroke Society of Australasia
Brisbane, Qld, Australia • 14-17 July 2016

*Extending Access
to Stroke Treatment*

Please join co-Trial Principal Investigator Professor Maree Hackett at the **AFFINITY Investigator Meeting** to be held at the SSA Conference in Brisbane. See details below:

Where: Asia Pacific Stroke Conference (combined with Stroke Society of Australasia)
Date: Saturday, 16th July 2016
Time: 5.30pm - 6.30pm (drinks and canapés will be provided)
Venue: Brisbane Convention & Exhibition Centre
Room: P9-10

The meeting will provide an opportunity to update our collaborators on the current status of the trial as well as invite new researchers to join our team. If you will be able to attend please notify the Trial Office via our global email address; (AFFINITY@health.wa.gov.au).

Site	Investigator Study Coordinator	Status	Milestone Reached	Site Open Since	Date of 1 st Rando	Date of Last Rando	Total
Sir Charles Gairdner Hospital SCGH	W/Prof Graeme Hankey A/Prof David Blacker Anne Claxton, Lindsey Bunce	ACTIVE	6	01/01/2013	14/01/2013	03/06/2016	47
Osborne Park Hospital OPH	Dr Kapila Abeyuriya Dr Poh Chua	ACTIVE	6	01/05/2013	28/06/2013	04/05/2015	9
Royal Melbourne Hospital RMH	Prof Stephen Davis Amy McDonald	ACTIVE	6	15/01/2014	28/02/2014	27/01/2016	14
Blacktown Hospital BLH	Prof Richard Lindley Camelia Burdusul	ACTIVE	6	08/07/2014	17/02/2015	15/01/2016	5
St Vincent's Hospital SVH	A/Prof Romesh Markus Kirsty Page	ACTIVE	6	12/08/2014	03/09/2014	09/10/2015	5
Royal North Shore Hospital RNSH	A/Prof Martin Krause Susan Day	ACTIVE	6	15/08/2014	19/02/2016	21/04/2016	4
Footscray and Sunshine Hospital FTSH	A/Prof Tissa Wijeratne Sherisse Celestino	ACTIVE	6	08/10/2014	27/10/2014	27/10/2014	1
Hawke's Bay Hospital HBH	Dr John Gommans Diana Schmid, Audrey Doak, Melissa Spooner	ACTIVE	6	26/09/2014	28/11/2014	28/01/2016	11
Campbelltown and Camden Hospital CCH	Dr Stanley Levy Beverley MacDonald	ACTIVE	6	03/10/2014	20/02/2015	07/06/2016	7
Wellington Hospital WH	Dr Harry Mc Naughton Lai-Kin Wong	ACTIVE	6	13/03/2015	15/06/2015	24/05/2016	5
Flinders Medical Centre FMC	Prof Andrew Lee Paul Stockle	ACTIVE	6	17/04/2015	-	-	0
Royal Prince Alfred Hospital RPAH	Prof Craig Anderson Alejandra Malavera	ACTIVE	6	22/04/2015	03/08/2015	26/05/2016	2
Wagga Wagga Base Hospital WWBH	Dr Martin Jude Katherine Mohr	ACTIVE	6	08/07/2015	14/10/2015	14/10/2015	1
Fiona Stanley Hospital FSH	Dr Darshan Ghia Gillian Edmonds Nicole O'Loughlin	ACTIVE	6	11/05/2015	20/05/2015	30/03/2016	22
Taranaki Base Hospital TBH	Dr Bhavesh Lallu Bronwen Pepperell	ACTIVE	6	03/07/2015	21/12/2015	13/05/2016	4
John Hunter Hospital JHH	Dr Jennifer White	ACTIVE	6	16/10/2015	-	-	0
Belmont Hospital BH	Dr Michael Pollack Dr Lauren Tarrant	ACTIVE	6	16/10/2015	14/10/2015	05/05/2016	3
Calvary Mater Newcastle CMN	Dr Elizabeth Pepper Emily Duckett	ACTIVE	6	16/10/2015	01/12/2015	01/03/2016	2
Rankin Park Rehabilitation Unit RPRU	Dr Michael Pollack	ACTIVE	6	16/10/2015	-	-	0
Calvary Health Care Bruce CHCB	Dr Yash Gawarikar Emma Siracusa	ACTIVE	6	22/07/2015	29/07/2015	17/05/2016	11
St John of God Midland SJOGM	Dr Timothy Bates Lynda Southwell	ACTIVE	6	04/03/2016	25/5/2016	25/5/2016	1
Shoalhaven District Memorial Hospital SDMH	Dr Jeremy Christley	ACTIVE	6	23/3/2016	-	-	0
Kingston Centre KC	Dr Peter New Megan O'Neill, Cameron Redpath, Toni Withiel	ACTIVE	6	18/5/2016	26/5/2016	26/5/2016	1
Casey Hospital CH	Dr Peter New Megan O'Neill, Cameron Redpath, Toni Withiel	ON HOLD	6	-	-	-	-
Lyell McEwin Hospital LMH	A/Prof Timothy Kleinig	Gov Prepared	2				
Hornsby Hospital HH	Dr Kong Chung Malcolm Kanard	Gov Prepared	2				
Manly Hospital MH	Dr Andrew Evans	Gov Prepared	2				
Prince of Wales Hospital POWH	Dr Pesí Katrak	Preparing Gov	1				
Caulfield Hospital CFH	Dr Peter New Cameron Redpath, Megan O'Neill	Ethics Pending	0				
Armidale Rural Referral Hospital ARRH	Dr Nihal Nanda Amanda Styles/Melissa Gill	Ethics Approved	1				
Royal Perth Hospital RPH	Site on hold no PI	INACTIVE	6	01/01/2013	11/01/2013	10/09/2015	78
Rockingham General Hospital RGH	Site on hold no PI	INACTIVE	6	01/10/2013	-	-	0
Swan District Hospital SDH	Clin/A/Prof Tim Bates	SITE CLOSED	6	10/05/2013	13/05/2013	18/09/2015	9



FINANCIAL SUPPORT

We are able to provide financial support to participating sites as follows:

AFFINITY Trial

- 1) Ethics / governance fee
- 2) Pharmacy costs
- 3) Therapeutics Goods Administration, Clinical Trial Notification fee
- 4) Per patient payment of A\$1000 for the completion of assessments

AFFINITY BM DNA/MRI Sub Study

Site investigators will be paid Aus\$200.00 for the baseline MRI and \$200.00 for the follow-up MRI of each consenting participant.

Site investigators will be paid Aus\$200.00 upon arrival at Pathwest, Perth of stored blood samples from each consenting participant.

Pathology and MRI cost will be covered as negotiated.

Feedback and Suggestions

We welcome any feedback or suggestions regarding the trial please email

Affinity@health.wa.gov.au

