ANZUP 1801

ANZUP Cancer Trials Group Limited

DASL-HiCaP Trial News

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Welcome to the second DASL-HiCaP newsletter

Despite the challenges faced by sites due to the outbreak of COVID-19, Australian sites have been recruiting well, and the **18th patient has now been randomised**. Particular congratulations to the teams at Fiona Stanley Hospital for already recruiting six patients and Calvary Mater Newcastle for recruiting five! We have 11 sites activated already. A number of additional sites are completing activation and local approval processes, and are expected to open in the coming months.

Thanks to everyone involved for all your hard work in these difficult times!

Recruitment by site

Site	Activation Date	Participants to date
Chris O'Brien LifeHouse	31/03/2020	2
Calvary Mater Newcastle	4/05/2020	5
Princess Alexandra Hospital	19/05/2020	2
Icon Cancer Centre - Gold Coast	18/06/2020	3
Fiona Stanley Hospital	23/06/2020	6
Total		**18**

"It has been great to see this important trial for men with high-risk localised prostate cancer able to be activated and start recruiting during this COVID-19 period. Congratulations to everyone involved and we look forward to opening the trial internationally later this year."

Professor Lisa Horvath,
Professor Scott Williams &
Professor Shomik Sengupta
DASL-HiCaP ANZ Leads

In collaboration with:

cancer trials ireland

Canadian Cancer Trials Group

pctc The Prostate Cancer Clinical Trials Consortium

NHMRC Clinical Trials Centre

We also acknowledge Bayer for their product and funding support:

BAYER

Trial sponsor:

THE UNIVERSITY OF SYDNEY

Screening patients: timing of imaging

To be eligible for DASL-HiCaP study enrolment, patients require diagnostic quality imaging of both the pelvis and the abdomen (CT or MRI), chest (CXR or CT) and a WBBS (Protocol v1.1 Schedule of Assessments, footnote (k)).

Some sites have contacted us with questions about the timing of this screening imaging (described in Schedule of Assessments footnote (i)), especially for patients who had commenced ADT before being considered for the study. The study chairs have now provided clarification on imaging timing:

- **If ADT has not been started**, then screening imaging must be performed within 60 days prior to randomisation.
- **If ADT has been started**, then screening imaging must be performed prior to randomisation, ***and*** within 60 days before starting ADT ***AND IS ALLOWED TO BE DONE UP*** to 30 days after starting ADT.

This will be clarified in an upcoming protocol amendment. If unsure about the timing of scans for a potential participant, please email the DASL study team (dasl@ctc.usyd.edu.au).

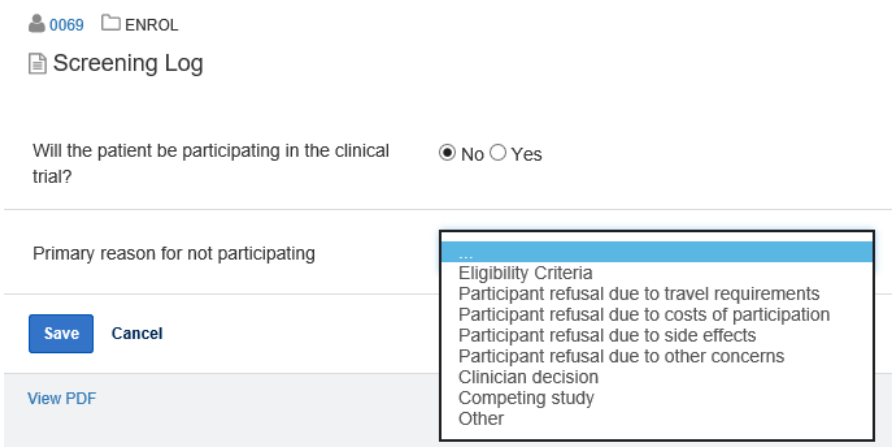
Note that if any additional scans are performed for study eligibility that would not be performed for standard of care, the patient must be consented to the study before these scans are performed.

Recording screening information in Medidata EDC

Screening information is extremely valuable to understand why recruitment may be progressing better or worse than forecast. For DASL-HiCaP, we will be collecting screening information in Medidata EDC to help us monitor recruitment closely.

A reminder to all sites to please record all patients approached (definition of approached: detailed chart/records review, spoken with patient and/or given a consent form) for participation in DASL-HiCaP in the EDC, regardless of whether they will be participating in the study or not. For non-participating patients, including patients who decline consent, the reasons for non-participation/screen failure should be recorded. Please note: for non-consenting patients, the Medidata participant ID generated must not be recorded on patient records.

DASL-HiCaP Screening Log in Medidata EDC:



In addition, the paper-based DASL HiCaP Screening log can be used to help you capture all patients approached for participation in the study, prior to entering them into the EDC. Use of this paper form is optional.

Data management reminders:

Thank you to our recruiting sites who have already been busy entering data in Medidata EDC. We've noticed that a common issue for sites is that data is not being entered on forms that sit outside of the visit folders.

These are:

1. **Consent form**: details of the full PISCF signed by the participant should be recorded for all randomised patients
2. **Study treatment form**: whenever study treatment or a background treatment is started, stopped or changed this should be recorded in the study treatment form. For your participants who have already commenced study treatment (darolutamide/placebo), LHRHA, radiotherapy or docetaxel, please ensure you have recorded each treatment as a new row on the study treatment form.
3. **Imaging form**: Please remember to enter the details of all required screening imaging (pelvis and abdomen (CT or MRI), chest (CXR or CT), and WBBS). Each scan should be entered as a separate row. If a PSMA PET was performed this should also be recorded on the imaging form.
4. **PSA form**: All PSA assessments performed as per the Schedule of Assessments should be recorded on the PSA form, including screening +/- baseline PSA assessments. For post-prostatectomy participants, two screening PSA results will be required to confirm persistent or rising PSA.
5. **AE form**: Please record any AEs that occur after randomisation on the study. If the exact start date of an AE is unknown, please enter the best estimate of AE start date. AE dates are required, and partial or unknown dates are not accepted.

For more information, please refer to the DASL eCRF completion guidelines or contact the DASL study team (dasl@ctc.usyd.edu.au).

Contact the team:

If your site has any questions about site start-up, patient eligibility, treatment schedules, or anything else, please don't hesitate to contact the study team at dasl@ctc.usyd.edu.au.

STUDY CO-CHAIRS

A/Professor Tamim Niazi

Professor Christopher Sweeney

Receiving ongoing ANZUP trial information

ANZUP members can log into the ANZUP website and update their profile to receive information on specific trials and subcommittees of interest. Go to: https://www.anzup.org.au/login.aspx

DASL-HiCaP key contacts

- **Clinical trial operations, CTC E:** dasl@ctc.usyd.edu.au
- **Study Co-Chairs - Chris Sweeney E:** Christopher.Sweeney@DFCI.HARVARD.EDU **and Tamim Niazi E:** tniazi@jgh.mcgill.ca
- **ANZUP Clinical Trials Operations - Nisha Rana E:** trials@anzup.org.au
- **Trial information:** https://anzup.org.au/content.aspx?page=dasl-hicaptrial