ANZUP 1801

ANZUP Cancer Trials Group Limited

DASL-HiCaP Trial News

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Welcome to the third DASL-HiCaP newsletter – April 2021

Despite ongoing challenges posed by COVID-19, our sites have been recruiting amazingly well, and we now have 155 patients randomised on the study, across 27 activated sites. March was a record month for the study, with 20 new patients recruited across our sites. Particular congratulations to the busy team at Fiona Stanley Hospital for recruiting a huge 46 patients already!

New regions opened

Congratulations to the team at Auckland Hospital for recruiting the first patient in New Zealand!

Canada has also been activated under the leadership of the Canadian Cancer Trials Group (CCTG). Congratulations to the Jewish General Hospital for recruiting the first Canadian patient, and marking 150 on the DASL-HiCaP trial!

"It was great to see DASL-HiCaP open for recruitment this month in Canada, after many months of negotiations and setbacks due to COVID-19. I look forward to the trial opening in more sites across Canada in the coming months."

A/Professor Tamim Niazi
DASL-HiCaP Co-Chair

In collaboration with:

cancer trials ireland

Canadian Cancer Trials Group

Memorial Sloan Kettering Cancer Center

pcdtc 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

Site recruitment:

Site	Country	Patients recruited
Fiona Stanley Hospital	Australia	46
Calvary Mater Newcastle	Australia	23
GenesisCare Newcastle	Australia	12
Princess Alexandra Hospital	Australia	11
Chris O'Brien LifeHouse	Australia	8
Icon Cancer Centre Gold Coast	Australia	8
Gosford Hospital	Australia	6
Royal Brisbane and Women's Hospital	Australia	6
The Townsville Hospital	Australia	5
Ashford Cancer Centre Research	Australia	5
Wollongong Hospital	Australia	4
ROPART	Australia	4
Campbelltown Hospital	Australia	4
St Vincent's Public Hospital, Sydney	Australia	2
St George Hospital	Australia	2
Peter MacCallum Cancer Centre (Bendigo Campus)	Australia	2
Royal Hobart Hospital	Australia	2
Liverpool Hospital	Australia	1
Peter MacCallum Cancer Centre	Australia	1
Peter MacCallum Cancer Centre (Moorabbin Campus)	Australia	1
Auckland City Hospital	New Zealand	1
Jewish General Hospital	Canada	1
TOTAL		**155**

TROG accreditation

We have recently partnered with the Trans-Tasman Radiation Oncology Group (TROG Cancer Research) in order to deliver high-quality radiation therapy accreditation for the study. As part of the site startup process for new sites, TROG will be emailing a brief supplementary questionnaire about proposed site RT procedures for the study in order to assist with determining whether any changes or additional action is required for accreditation. Sites that are already activated on the study may continue as normal, but we will be asking these sites to also submit questionnaires and go through this process retroactively once our new sites are completed.

IDSMC Letter of Recommendation

The ANZUP Independent Data and Safety Monitoring Committee (IDSMC) met on 3 December 2020 to review DASL-HiCaP. The IDSMC recommended that the DASL-HiCaP Trial continue with **no IDSMC safety concerns**.

COVID-19 vaccination guidance

Trial participants should be vaccinated against COVID-19 according to the locally applicable standard of care and guidelines. Sites should follow their standard local policies regarding eligibility for vaccination, and its timing, for participants undergoing the same (or similar) treatments as part of routine clinical practice.

Trial participation does not affect a trial participant's eligibility or timing for vaccination. Vaccination should not affect a participant's participation in the DASL-HiCaP trial. Vaccination should not affect the schedule of assessments, eligibility, screening, or randomisation. Vaccination does not require withdrawal from the DASL-HiCaP trial.

If new pertinent information arises during the course of the vaccination programs globally, then updates to this guidance will be provided. Please contact the DASL-HiCaP study team (dasl@ctc.usyd.edu.au) or your local regional coordinating centre for more information if required.

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Consenting patients – tips and reminders

Ensuring that the informed consent process is done correctly is taken very seriously by the DASL-HiCaP team, and is also taken very seriously by various regulatory bodies. We're sure your teams are providing the required information to patients in an appropriate way so they can make an informed decision, but it's also important to follow all the procedural requirements. Here are some key points that sites sometimes trip up on:

- Make sure the patient is eligible before they are randomised! Check each inclusion and exclusion criterion specifically, and document the ones requiring numerical values (eg blood tests) to be sure they are in the acceptable range
- Ensure that the patient is given sufficient time to read the PICF and discuss with family/ friends before they sign the initial consent. Don't consent patients on the same day they are first given the Patient Information and Consent Form (PICF), no matter how eager they might be!
    - If they need to reconsent to an amended PICF later in the study, patients can generally be reconsented at the same visit they first receive the amended PICF
- Ensure patient consent is fully documented in your source notes. If the original PICF was ever misplaced (it happens!), there should be enough info in source to confirm exactly what took place
    - Consider something like "Patient consented to DASL-HiCaP main PICF local version X dated DD/MM/YY. All questions answered and copy given to patient. Patient consented/did not consent to translational research/future extended research"
    - In countries with separated translational research PICFs, ensure that the version and date of these forms is documented as well
- Ensure that the patient signs the consent in the presence of the investigator. If the patient has already signed their copy at home, get a fresh copy for them to sign at the consenting visit
- Ensure that all the details in the PICF are complete and correct. In particular, ensure that patients have selected "yes" or "no" to both the optional translational research questions, as this is frequently missed
- Ensure that the original PICF (all pages) is kept on site, and the patient is given a copy
- Ensure that any reconsenting is performed in a timely manner. Generally, this will be the first visit after the amended PICF has been approved for use by the relevant regulatory/governance body
- Please ensure all consents and reconsents are entered into the Consent eCRF in Medidata (this is not applicable at Canadian sites)
- Follow any additional requirements that are specific to your country and/or local ethics/regulatory bodies

STUDY CO-CHAIRS

Chris Sweeney and Tamim Niazi

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.

DASL-HiCaP key contacts

- **Clinical trial operations, CTC E:** dasl@ctc.usyd.edu.au
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