ANZUP Cancer Trials Group Limited

DASL-HiCaP Trial News

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Congratulations on reaching 50% recruitment!

A huge congratulations to the entire DASL-HiCaP study team, especially to our site investigators and coordinators, on reaching this important milestone. There are now 551 participants randomised on DASL-HiCaP around the world, half-way to our total recruitment target of 1100.

We hope to complete recruitment by mid-2023.

A special mention also to our top recruiting sites: Fiona Stanley Hospital (Site PI Tee Sin Lim), Calvary Mater Newcastle (Site PI Jarad Martin) and Odette Cancer Centre - Sunnybrook Hospital (Site PI Hans Chung). Also a warm welcome to the newest sites to join the study: Centre Hospitalier de l'Universite de Montreal (Site PI Marie-Claude Beauchemin) and we also activated our first teletrials site at Latrobe Regional Hospital in Victoria, under the supervision of the Alfred Hospital team led by Site PI Jeremy Millar.

Study recruitment

Country	# Sites activated	# Participants randomised
Australia	28	359
Canada	11	113
New Zealand	4	30
US	6	32
Ireland	3	11
UK	5	6
Global total	57	551

"Having reached the 50% milestone, we are very confident the study will be accrued. Moreover, in a few years we will also know whether the addition of darolutamide to radiation and ADT increased the number of patients who do not recur. Having this data and darolutamide available for adjuvant therapy will be an important option for our patients given its favourable side effect profile and less interactions with other drugs patients may be taking."

Professor Chris Sweeney
DASL-HiCaP Study Co-Chair

Paxlovid advice:

We've recently distributed advice on the use of Paxlovid in DASL-HiCaP participants.

Paxlovid is a 5-day, two drug anti-SARS-CoV-2 regimen containing the antivirals nirmatrelvir and ritonavir, which have potential drug-drug interactions with drugs metabolised by CYP3A or which inhibit/induce CYP3A. Darolutamide is a weak CYP3A inducer and therefore has the potential to interact with Paxlovid. If a participant enrolled on DASL-HiCaP is prescribed paxlovid upon reporting a positive COVID-19 test, **we recommend withholding study medication for the duration of Paxlovid administration**.

IDSMC Letter of Recommendation

The ANZUP Independent Data and Safety Monitoring Committee (IDSMC) met on 6 December 2021 to review DASL-HiCaP. The IDSMC recommended that the DASL-HiCaP Trial continue with no IDSMC safety concerns.

Protocol amendment

Version 3.1 of the protocol has recently been approved by the lead Australian ethics committee and will be rolled out to sites by their coordinating centres in due course. This amendment includes clarifications of the screening requirements relating to PSA testing and imaging, based on feedback from our sites.

Patient follow-up

We understand that patients may have to stop study treatment early, due to toxicity or patient choice or other circumstances. Per the protocol, patients who have stopped study treatment early should continue to be followed according to the relevant on-treatment assessments for the first two years, unless this is no longer feasible. Patients also may or may not continue with the background treatments (LHRHA/radiation/docetaxel), and this information is important to capture.

Please confirm when a patient comes off study treatment:

- Would it be appropriate (and would the patient be willing) to continue study visits in follow-up (per the schedule of assessments) with one or more of the visits missed/delayed due to the unavoidable circumstances?
- And if not, would the patient still be willing to be followed for ongoing disease status/subsequent treatment etc?

Follow-up information is crucial for this study, as metastasis-free survival is our primary study endpoint, and every patient who withdraws completely from the study reduces our ability to determine if the study treatment is effective (as well as other endpoints).

Please make every effort to confirm the extent of follow-up that the participant is willing to consent to, while of course being mindful not to pressure them.

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.study@sydney.edu.au.

PSMA PET lesions

Please remember that PSMA PET lesions do not constitute a metastasis event unless also evident on conventional imaging.

Collaborators

In collaboration with:

We also acknowledge Bayer for their product and funding support:

Trial sponsor:

STUDY CO-CHAIRS

Chris Sweeney and Tamim Niazi

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#ANZUP22 ASM – 10-12 July - Adelaide

DASL-HiCaP key contacts

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