

# DASL-HiCaP Trial News







[www.anzup.org.au](http://www.anzup.org.au)

## Congratulations on reaching two-thirds recruitment!

DASL-HiCaP is now close to being fully-activated globally, with a whopping 71 sites in total (and even more satellite sites!). Thanks to all the study teams for your extraordinary efforts to get this study up and running at each of your sites, and a very warm welcome to our newest sites!

With the excellent global uptake of the study, recruitment is steaming ahead at full pace, and we have now recruited 748 of the planned 1100 patients total for the study. Congratulations again to GenesisCare Fiona Stanley Hospital for their continued incredible recruitment of 94 patients, and to Odette Cancer Centre – Sunnybrook Hospital in Canada for recruiting 44 patients in just over a year.

### Study recruitment (at 24 October 2022)

Country	# Sites activated	# Participants randomised
 Australia	29	440
 Canada	17	182
 New Zealand	3	40
 US	8	47
 Ireland	7	19
 UK	7	20
<b>Global total</b>	<b>71</b>	<b>748</b>

*“With a global effort, DASL-HiCaP is at two-thirds accrual and on track to complete accrual mid 2023. Great work team DASL-HiCaP! This progress is very timely given the possibility ENZARAD with enzalutamide and ATLAS with apalutamide in the primary radiation setting for high-risk localised disease may read-out in 2023. DASL-HiCaP’s use of darolutamide with a lower adverse event profile for some patients and inclusion of patients in the very high-risk post prostatectomy salvage radiation setting are two very unique features which ensure DASL-HiCaP will be relevant and add valuable data to the field and potentially increase treatment options for our patients.”*

**Prof Christopher Sweeney**  
**DASL-HiCaP Study Co-Chair**

## IDSMC Letter of Recommendation

The ANZUP Independent Data and Safety Monitoring Committee (IDSMC) met again on 28 July 2022 to review DASL-HiCaP. The IDSMC recommended that the DASL-HiCaP Trial continue with no IDSMC safety concerns.

## End of treatment

Time flies, and we are now at the point where some patients are reaching the end of their two years of study treatment. For these patients, the Week 84 visit will be the last drug dispensation, and all patients should stop study treatment exactly 96 weeks after randomisation, regardless of whether there were any drug interruptions in the treatment period. It won't always be possible to schedule patient visits at this exact date, so please remind patients where necessary that they should stop taking their tablets.

There is also no formal 30-day follow-up visit on DASL, but all AEs that start up to 30 days after ending treatment do still need to be entered in the eCRF. AEs after this do not need to be recorded in the eCRF. AEs should be reviewed at the Week 104 visit, so all relevant post-treatment AEs can be captured at this time.

## Study drug returns

The initial batch of study drug shipped to sites will be expiring soon, on 31 Dec 2022. It will now be even more important to ensure that patients are returning all their bottles of study tablets (whether empty or not) at each visit, to avoid the possibility of patients accidentally taking expired drug. We understand that patients are human and will occasionally forget to bring tablets in, or accidentally misplace or throw out bottles, but we ask that you remind patients of the tablet requirements and the importance of returning drug.

If drug returns at your site come directly to pharmacy, we strongly suggest ongoing communication between pharmacy and the study team, so that coordinators and investigators are aware when drug is not being returned or when there are anomalies in the return counts, and can follow up with patients as necessary.

If a patient is having repeated trouble returning all their bottles, please ensure that none of their unreturned drug is expired, and consider methods of reminding that patient about their returns. Please get in touch with us at [dasl.study@sydney.edu.au](mailto:dasl.study@sydney.edu.au) if you have any questions or concerns about a patient's drug returns or compliance.

## Nodal irradiation

The central dogma for RT in this study is to treat the primary (or bed) along with regional nodes in all cases. This was based on extensive discussions of what was an acceptable standard of care across multiple regions internationally during the study development. The protocol section 5.7 Radiotherapy Treatment Plan states "All participants will undergo curative-intent RT to the prostate or prostate bed as well as the pelvic LNs using EBRT". The RT manual offers basic guidance on how RT can be delivered to the protocol-mandated volumes allowing for what is likely to be significant local variation in practice globally - hence the flexible wording of that document. This wording does not override any protocol-mandated directives such as pelvic nodal coverage, however. We can however consider specific cases of protocol variation where a clinical justification has been documented and lodged with the study management.

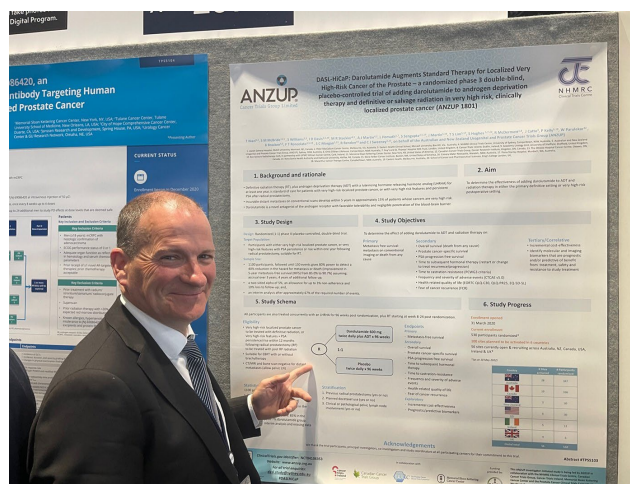
## Scanning for suspected relapse

At this stage in the study, some patients are unfortunately showing indications of relapse of their disease. A reminder that follow-up imaging on this study, at PSA progression and at subsequent timepoints, has the same requirements as screening imaging: imaging must include diagnostic quality imaging of both the pelvis and the abdomen (CT or MRI), chest (CXR or CT), and a whole-body bone scan. PET may be additionally performed but is not a substitute for the protocol-required imaging including bone scan. Omission of conventional imaging in this setting is a significant protocol deviation, because it affects the interpretation of the study's primary endpoint.

## DASL-HiCaP at #ASCO22

It was great after two years of the ASCO Annual Meeting being virtual, to see people back to face-to-face in Chicago. DASL-HiCaP featured as a Trial in Progress poster - presented by Study Co-Chair Christopher Sweeney.

[You can view the poster here.](#)



## Collaborators

*In collaboration with:*



Memorial Sloan Kettering  
Cancer Center



*We also acknowledge Bayer  
for their product and  
funding support:*

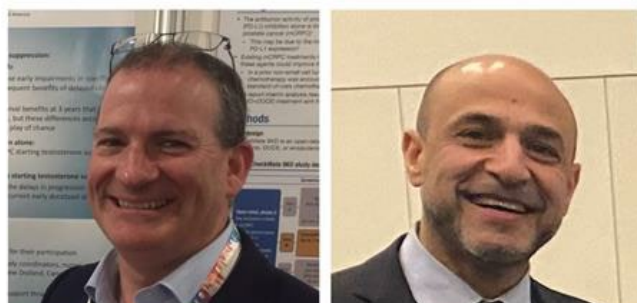


*Trial sponsor:*



## STUDY CO-CHAIRS

**Christopher 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.study@sydney.edu.au](mailto:dasl.study@sydney.edu.au).

## DASL-HiCaP key contacts

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