ANZUP 1801

ANZUP Cancer Trials Group Limited

DASL-HiCaP Trial News

www.anzup.org.au

Welcome to the first DASL-HiCaP newsletter

The first patient enrolled today marks the start of the journey to recruit and follow up 1,100 eligible patients from over 100 cancer centres across Australia, New Zealand, US, Canada, UK and Ireland. Our hope is that this trial might show new ways of improving outcomes for men with prostate cancer.

The DASL-HiCaP trial is designed to assess whether this novel hormone treatment, darolutamide, added to standard therapy can lessen the risk of recurrence of prostate cancer in men with prostate cancer with features with a high risk of spreading to other parts of the body. The patients in this study will be men treated with standard testosterone suppression along with radiation, or radiation after surgery.

Thank you for your support and participation.

Chris Sweeney and Tamim Niazi
DASL-HiCaP Study Co-chairs

COVID-19

The DASL-HiCaP Trial Executive Committee (TEC) have continued to meet on a regular basis to review and consider the possible impacts of the COVID-19 pandemic on trial activation, recruitment, study treatment and follow-up. After consultation with local sites, we made the decision to proceed with activation of the study and we are pleased to announce we opened our first site, Chris O'Brien Lifehouse, on 31 March 2020, followed by Townsville Hospital on 9 April. We are continuing to support sites in start-up activities to prepare for activation. If your site is able to continue with Research Governance Office (RGO) submission, essential document collection, system training, Site Initiation Visit, etc. at this time, please do so.

You will have recently received a set of COVID-19 Operational Guidelines specific for the study, with guidance on how to approach each visit/assessment, and alternate methods of carrying these out. Follow-up of participants including clinic visits should be conducted as per standard of care at your site. If your site is implementing mechanisms for clinical assessments, blood tests, and imaging to be done remotely, e.g. via telehealth, external laboratories and external imaging services closer to patients' homes, then these options are allowed by the DASL-HiCaP protocol as institutional standards of care. Please ensure that you track any deviations or changes in site procedures in the COVID-19 Deviation Log, and provide an updated log fortnightly to the CTC at **dasl@ctc.usyd.edu.au**.

In collaboration with:

cancer trials ireland · Canadian Cancer Trials Group · DANA-FARBER CANCER INSTITUTE · pcctc The Prostate Cancer Clinical Trials Consortium · NHMRC Clinical Trials Centre

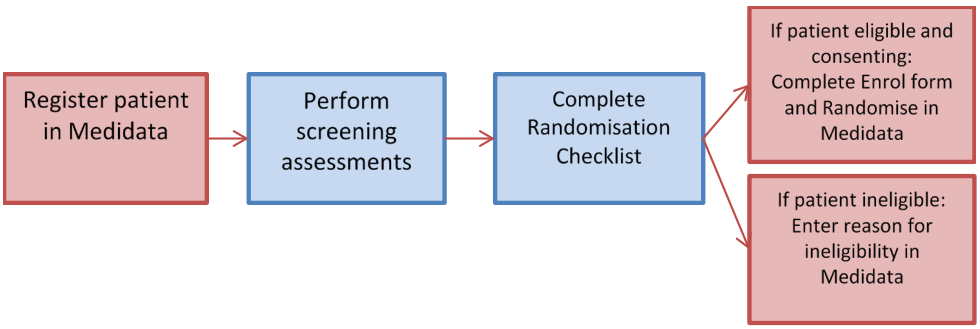
We also acknowledge Bayer for their product and funding support:

BAYER

COVID-19 will be considered a concurrent illness in this study protocol. Participants with suspected or confirmed COVID-19 are ineligible for enrolment in the study until after they have recovered fully from COVID-19.

If your site is not expecting to recruit patients at this time, but is able to continue with Research Governance Office (RGO) submission, essential document collection, system training, SIV etc at this time, then please do so. We are performing all SIVs by teleconference, please contact us at **dasl@ctc.usyd.edu.au** to schedule a time.

Patient registration and randomisation process



The DASL-HiCaP patient enrolment process commences with patient informed consent, and lead HREC has confirmed that during the COVID-19 pandemic, remote consent is permissible (see the COVID-19 Operation Guidelines for details of the procedure that is required to be followed). Patient registration is then performed in Medidata, which should be done for all patients considered for the study. The reason for non-enrolment should be entered for patients who decline consent or screen fail.

The Randomisation Checklist provided in your Investigator Site file should be completed by an investigator for every consented participant. If the participant is eligible, enter the relevant data into the eCRF and you will be able to proceed to randomisation. Randomisation will trigger the allocation of the first kit of study drug (darolutamide or placebo), which should be commenced within 7 days. Questions relating to enrolment, Medidata user accounts and randomisation procedure should be directed to **dasl@ctc.usyd.edu.au**.

Study team introduction

ANZUP:
Study Co-chairs: Chris Sweeney and Tamim Niazi
ANZUP Group Chair: Ian Davis
ANZ lead medical oncologist: Lisa Horvath
ANZ lead radiation oncologist: Scott Williams
ANZ lead urologist: Shomik Sengupta
CEO: Marg McJannett
Clinical Research Fellow: Felicia Roncolato
Research Manager: Nisha Rana
Communications and Media Manager: Nicole Tankard

CTC:
Clinical Lead: Martin Stockler
Statistician: Andrew Martin
Trial Operations Lead: Karen Bracken
Trial Operations Coordinator: Jason Todd
Clinical Data Manager: Savita Iyer
Clinical Trials Assistant: Muslima Rahman
Translational Research team: Sonia Yip and Garry Chang

We also look forward to welcoming our regional coordinating centres to the study.

Contact us via email: dasl@ctc.usyd.edu.au which is the trial mailbox for all your study related questions.

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 Research Manager Nisha Rana E:** nisha.rana@anzup.org.au
- **Trial information:** https://anzup.org.au/content.aspx?page=dasl-hicaptrial