ANZUP
Cancer Trials Group Limited

ENZA-p Trial News

www.anzup.org.au

Welcome to the first ENZA-p newsletter

The first of 160 patients was randomised on Monday 17 August at Austin Hospital – a huge thank you and congratulations to all involved for your hard work in reaching this milestone! ENZA-p opened its first site, St Vincent's Hospital Sydney on 7 August 2020, closely followed by Austin Hospital later the same day and Peter MacCallum Cancer Centre on 12 August. Another nine sites are completing local approval processes and are expected to open in the coming months.

A message from Study Chair: Associate Professor Louise Emmett

"The ENZA-p trial is an exciting leap forward, building on recent work by ANZUP in Lu-PSMA therapy for metastatic prostate cancer, and advances in science, to evaluate treatments that work better in combination. The ENZA-p trial will evaluate whether adding Lu-PSMA to enzalutamide overcomes treatment resistance in men with metastatic prostate cancer, deepening and prolonging treatment response and improving quality of life. We couldn't find a better team to be working on this problem. Thanks ANZUP!"

Study team introduction

Study Chair: Associate Professor Louise Emmett

ANZUP Team (study sponsor):
Chair: Ian Davis
CEO: Marg McJannett
Clinical Trial Operations Manager: Nisha Rana
Clinical Trials Project Manager: Thomas Cusick
ANZUP Clinical Research Fellows –
Shalini Subramaniam, Alison Zhang & Jane So

Contact us:

Email: enza-p@ctc.usyd.edu.au which is the trial mailbox for all your study related questions or trials@anzup.org.au for any sponsor related queries.

CTC Team:
Clinical Lead – Martin Stockler
Project Manager – Jenna Mitchell
Trial Coordinator – Ailsa Langford
Data Manager – Rayn Penaflor
Clinical Trials Assistant – Kathleen Harwood
Statistician – Andrew Martin
Translational Research team – Sonia Yip & Garry Chang

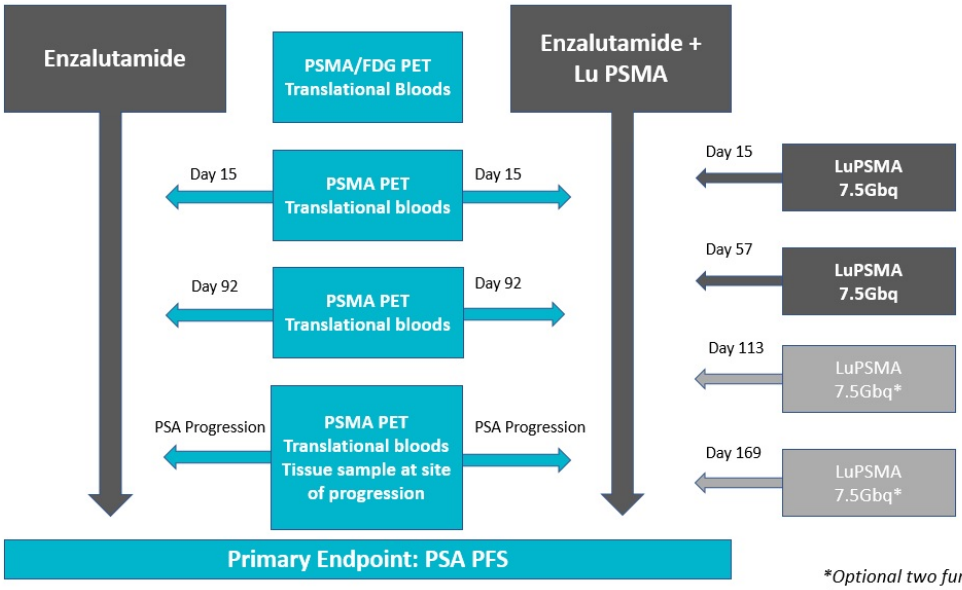
ANZUP Cancer Trials Group Limited

What is ENZA-p?

A randomised phase II trial using PSMA as a therapeutic agent and prognostic indicator in men with metastatic castration-resistant prostate cancer treated with enzalutamide (ANZUP 1901).

Primary Aims:	
A.	Evaluate synergistic combination therapies in men at high risk of early treatment failure with single agent enzalutamide
B.	Develop and validate more accurate prognostic and predictive decision making tools for mCRPC
C.	Use translational research to identify patterns of resistance with a view to developing more effective therapy combinations

AIM A:



**Optional two further Lu-PSMA doses to be determined following Day 92 ^{68}Ga-PSMA PET*

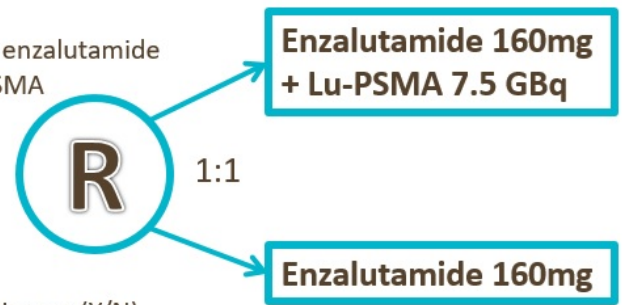
AIM B,C:

Eligibility

Confirmed mCRPC with PSA rising and ≥10 ng/mL
No chemotherapy for mCRPC
≥ 2 high risk features for early failure on enzalutamide
Baseline PSMA SUV max > 15 on ^{68}Ga-PSMA

Stratification

Study site
Volume of disease (>20 vs ≤20 sites)
Early docetaxel for castration-sensitive disease (Y/N)
Early abiraterone for castration-sensitive disease(Y/N)

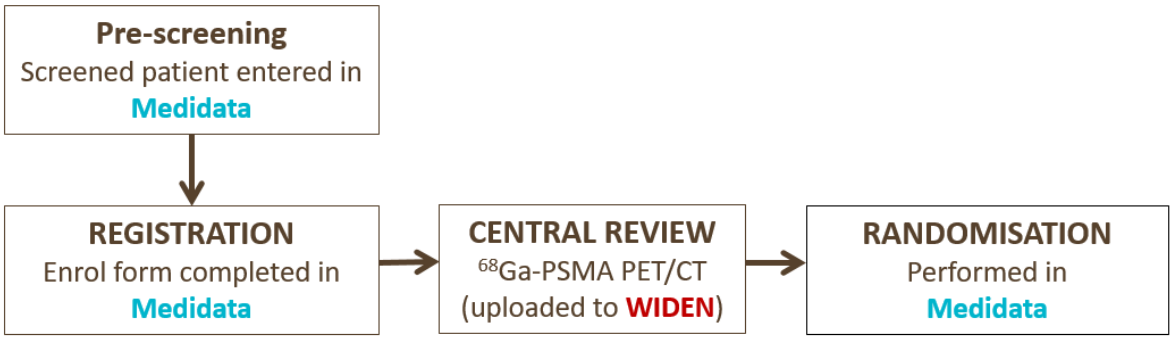


Endpoints

PSA PFS
Radiographic PFS
PSA Response Rate
Pain response & PFS
Clinical PFS
HRQOL
AEs
OS
Translational*

In collaboration with:

Patient registration and randomisation process



Pre-screening

Any patient identified as potentially eligible for ENZA-p in clinic, MDT, etc. and approached for the trial is considered pre-screened and should be logged in Medidata.

This does not involve the collection of any patient information.

- If the patient is not eligible and/or unwilling to participate then mark the patient as 'Not participating' in the Medidata 'Screening' form along with the primary reason.
- If the patient is eligible and willing to participate then mark them as participating on the 'Screening' form and proceed with Medidata **Registration.**

Registration

If the patient is deemed eligible on all criteria except those involving PET imaging, then register the patient in Medidata by completing the main section of the 'Enrol' form. This step is required in order to add the patient to WIDEN. You can now proceed with the PSMA and FDG PET imaging.

Central review

Within 48 hours of screening PET imaging, upload the scans to WIDEN. The scans will be reviewed within 48 hours by a team of central reviewers and you will receive an email confirming in/eligibility.

- If the WIDEN email states that the patient is ineligible, then indicate this at the bottom of the Medidata 'Enrol' form. No further data entry is required.
- If the WIDEN email states that the patient is eligible, then complete the remainder of the Medidata 'Enrol' form and proceed with **Randomisation.**

Randomisation

Complete the Medidata 'Stratification' and 'Rand' forms to randomise the patient.
*For any questions relating to this process, please contact **enza-p@ctc.usyd.edu.au**.*

PSMA and Lu-PSMA for validation runs

Before any site can be activated on ENZA-p, ARTnet certification must be in place for the following:

- Lu-PSMA production
- Ga-PSMA production
- PET camera

Note that a virtual site visit is also required as part of the accreditation process. For sites who were previously accredited as part of the TheraP trial, only one successful validation run is required for the above. For new sites, three successful validation runs must be completed. *Please contact **enza-p@ctc.usyd.edu.au** with queries relating to validation or to order PSMA/Lu-PSMA.* Please place orders as soon as possible to prevent delays.

Ongoing document/upload requirements

A reminder that the following are required for every randomised patient throughout the ENZA-p trial:

- Up to date screening information in Medidata
- WIDEN image uploads (ALL trial imaging, including CT, WBBS, SPECT/CT, PSMA PET, FDG PET)
- De-identified CT and WBBS scan reports
- Translational blood collection forms

*Please send documents to the trial mailbox at **enza-p@ctc.usyd.edu.au**.*

ENZA-p key contacts

- **Clinical trial operations, CTC E:** enza-p@ctc.usyd.edu.au
- **Coordinating PI: Louise Emmett E:** emmetthruby@gmail.com
- **Sponsor queries (payments, contracts) Nisha Rana E:** trials@anzup.org.au
- **Trial information:** https://anzup.org.au/content.aspx?page=enza-ptrial