ANZUP 1901

ANZUP Cancer Trials Group Limited

# ENZA-p Trial News

www.anzup.org.au

## Welcome to the second ENZA-p newsletter – April 2021

Many thanks to our 10 activated sites for all your support and in particular congratulations to our lead recruiters, St Vincent's and the Austin for a fantastic start.
We currently have 38 of 160 patients randomised.

Please continue to discuss ENZA-p at your MDTs and encourage your colleagues to refer any eligible patients if and when possible.

## Site accrual

| Site | Recruitment |
|---|---|
| St Vincent's Sydney | 11 |
| Austin | 9 |
| Peter MacCallum | 5 |
| Royal Brisbane & Women's | 4 |
| Royal Adelaide | 4 |
| The Alfred Hospital | 2 |
| Calvary Mater Newcastle | 2 |
| Fiona Stanley | 1 |
| Northern Cancer Institute | 0 |
| Sir Charles Gairdner | 0 |
| TOTAL | 38 |

**Study Chair:**
**Professor Louise Emmett**

## Please continue to screen potential patients who may be eligible for ENZA-p:

- Men with metastatic castrate-resistant prostate cancer
- No prior treatment with docetaxel (castration-sensitive setting permitted)
- Suitable for treatment with enzalutamide
- Progressive disease with rising PSA ≥ 5 ng/mL
- At least 2 risk factors for early enzalutamide failure:
  - LDH ≥ ULN
  - ALP ≥ ULN
  - Albumin <35g/L
  - >5 bone metastases
  - Visceral metastases
  - De novo metastatic disease (M1) at initial diagnosis
  - <3 years since initial diagnosis
  - PSA doubling time <84 days
  - Pain requiring opiates for >14 days
  - Prior abiraterone

## Re-screening of screen-failed patients

Re-screening of patients who have previously been screen-failed on the screening PET scans is not permitted unless specifically requested by the study team.

For patients who were screen failed prior to PET scans (e.g. due to low PSA), these patients can be re-screened. Please ensure that re-consent is obtained prior to commencing study specific re-screening assessments.

## Patient identifiers

A reminder that patient identifying information must be removed from email correspondence and documents prior to sending to the NHMRC CTC. Please review all site email chains and attachments for identifiers prior to forwarding to the ENZA-p mailbox.

## Data entry tips

A few Medidata tips to help with smooth data entry:

- Complete the TA Date form in the IMAGING folder BEFORE completing the BONE Baseline and SOFT TISSUE Lesions forms.
- Complete the PSA form: it is expected that 2x PSA results will be reported within 28 days prior to randomisation, which will confirm a rising PSA and be >5ng/mL.
- VISIT folders should be completed for every study visit where a medical oncology assessment is completed, i.e., Day 15, 43, 71, 99, etc. The first VISIT folder completed ('VISIT (1)') should correspond to the Day 15 visit and QOL forms are 'Not required at this visit'.
- If a patient is randomised to Lu-PSMA, a VISIT folder does NOT need to be completed on Day 57, 113, etc. – instead, please ensure a new row is added to the Study Treatment form to record details for each Lu-PSMA treatment cycle.
- The End of Treatment form should be completed when the patient stops study treatment and the 'last dose' dates should match those reported on the Study Treatment form. If the reason for ceasing study treatment is 'Disease progression', corresponding details are expected to be reported in the relevant Med Onc Assessment/Follow-up Status form (in the VISIT/FUP folder) and/or BONE/SOFT TISSUE Lesion forms (in the IMAGING folder), as applicable.

## In collaboration with:

ANZUP Cancer Trials Group Limited

## Time in Motion data collection

We recently circulated instructions and a worksheet for the collection of Time in Motion resource use data by Nuclear Medicine teams. The worksheet should be completed once for each Lu-PSMA patient, preferably at their first Lu-PSMA dose.

Record the time spent by the patient in the nuclear medicine department, as well as the time spent on patient care by Nuclear Medicine department staff over the two days of Lu-PSMA administration and post-dose SPECT/CT.

The information should then be entered into WIDEN at the time of SPECT/CT upload.

As always, please don't hesitate to contact **enza-p@ctc.usyd.edu.au** if you have any questions.

## Translational Research

***Blood for translational research***

**For all patients:**

- Collect, process and store the standard ENZA-p serial bloods (3 timepoints) at baseline, Day 92 and first progression (PSA or radiological) from all patients
  ***Reminders****: centrifuge at 4 degrees; process and freeze samples within 1 hr of phlebotomy*
- Courier bloods to (Epic Sciences, Singapore) in real-time (on the same day). This is for the circulating tumour cells study

**At selected sites only**:

- Also collect blood to recover peripheral blood mononuclear cells (PBMCs)

**Data entry in EDC:**

- Enter the blood collection details in Medidata as soon as possible
- If a blood collection was missed, enter the reason in the eCRF

***Tissue for translational research***

- Biopsies at baseline and progression are collected at selected participating sites only and optional for patients.
  - Fresh tissue biopsies are processed and cryopreserved at site
  - Enter the tissue collection details in Medidata as soon as possible
- Archival tissue (all patients)
  - You will be advised by the ENZA-p coordinating centre when to retrieve tissues

## ENZA-p key contacts

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