ANZUP 2001

ANZUP Cancer Trials Group Limited

EVOLUTION Trial News

www.anzup.org.au

Welcome to the first EVOLUTION newsletter

Our first of 100 patients was randomised last month on 4 July and commenced treatment on 18 July – a huge thank you and congratulations to all involved for your hard work in reaching this milestone! EVOLUTION opened its first site, the Peter MacCallum Cancer Centre, on 4 May 2022, followed by the Royal Adelaide Hospital on the 4 July and Austin Hospital on 13 July. Another five sites are working towards site activation and are expected to open over the next 1-3 months.

Study Chair: Associate Professor Shahneen Sandhu

"We're excited to be opening the first ever study to test the effectiveness of combining ^{177}Lu-PSMA with cancer immunotherapy. We hope this study will lead to better and more durable responses for people with prostate cancer."

What is EVOLUTION?

A Phase II Study of Radionuclide ^{177}Lu-PSMA Therapy versus ^{177}Lu-PSMA in Combination with Ipilimumab and Nivolumab for Men with Metastatic Castration Resistant Prostate Cancer (ANZUP 2001).

Study team introduction

Study Chair: Associate Professor Shahneen Sandhu
Deputy Chair: Professor Louise Emmett

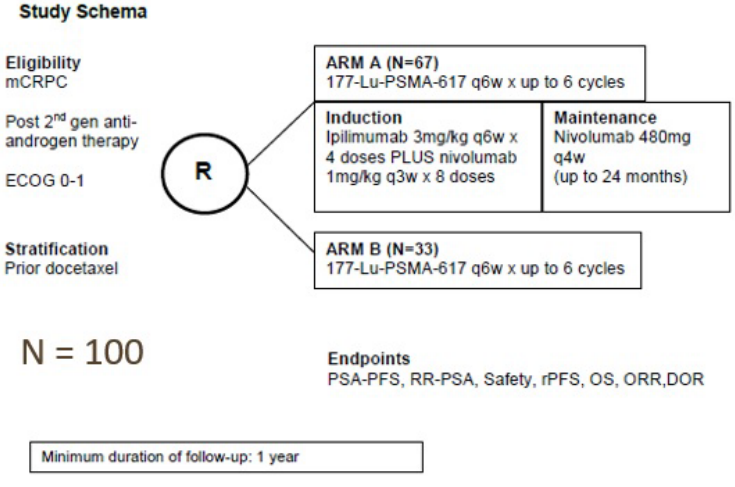
Email: evolution.study@sydney.edu.au which is the trial mailbox for all your study related questions or trials@anzup.org.au for any sponsor related queries.

What is EVOLUTION? Cont…….

Objectives:	
Primary	To determine the effect of treatment on PSA Progression Free Survival (PSA-PFS) at 1 year
Secondary	To evaluate: 1. Prostate specific antigen (PSA) response rate (RR-PSA). 2. Adverse events (AE) according to CTCAE v5.0. 3. Radiographic PFS 4. PSA-PFS time 5. Overall survival time (OS) 6. Objective response rate (ORR, RECIST1.1) 7. Duration of response (DOR) and duration of disease control by RECIST1.1 for soft tissue 8. Health-related quality of life (EORTC QLQ-C30 and Patient DATA Form)
Tertiary & Correlative	To evaluate exploratory biomarkers including: 1. SPECT at 12 weeks to assess response as a predictor of clinical benefit 2. Local tumour and systemic immunological responses to define determinants of response and resistance 3. Molecular signatures using tumour tissue, PBMCs and ctDNA as possible predictors of response

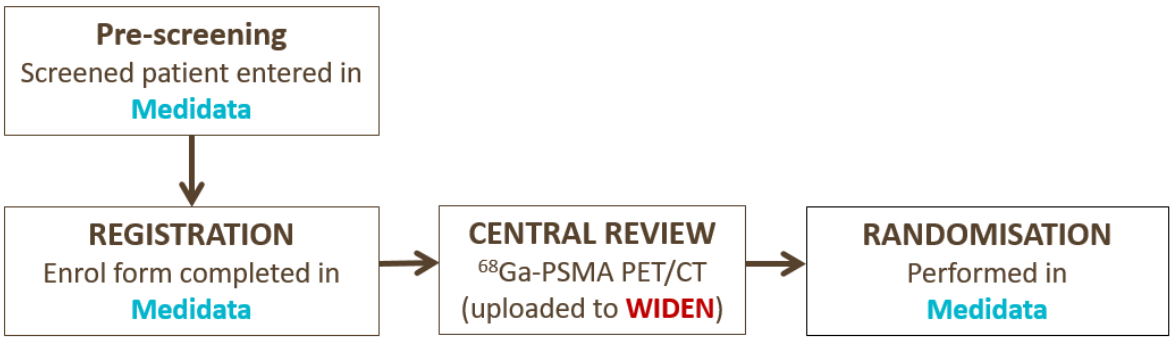
Study Schema:

Open label, randomised, stratified 2-arm, multicentre phase 2 clinical trial



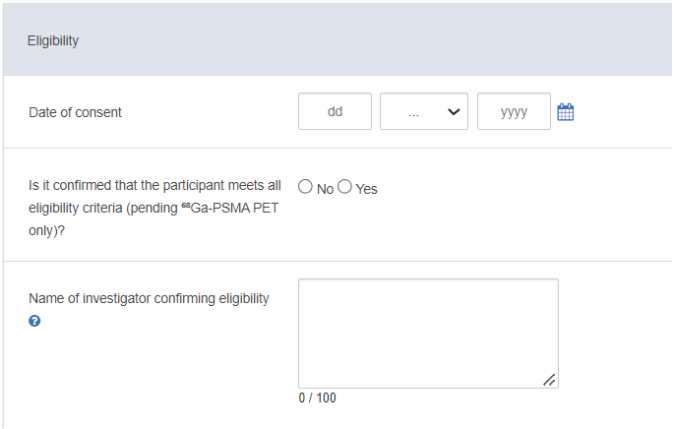
In collaboration with:

Patient registration and randomisation process



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 eligibility.

- If the WIDEN email states that the patient is ineligible, then indicate this at the bottom of the Medidata 'Enrol' form. Then proceed to the 'Screening Log' folder, select 'No', and provide the primary reason the patient will not be participating in the study.
- 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 'Rand' forms to randomise the patient. The patient can then proceed to the Baseline visit. **Please note that the Baseline visit should occur within 7 days of C1D1, which is different to what is currently in the protocol. This is intended to be amended shortly.**

For any questions relating to this process, please contact **evolution.study@sydney.edu.au**.

PSMA and Lutetium for validation runs

Before any site can be activated on Evolution, ARTnet certification must be in place. Due to various sites participating in one or both of the TheraP/ENZA-p trials, the exact requirements for ARTnet certification differ by site. The study team from the CTC will advise further as your site proceeds towards activation.

Please contact evolution.study@sydney.edu.au with queries relating to validation or to order PSMA/Lutetium. 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 EVOLUTION 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 all non-imaging documents to the trial mailbox at **evolution.study@sydney.edu.au**.

Translational Research

Please note that this study will be using a new courier for the pickup of blood samples in the future. When this process has been finalised, the lab manual will be updated with the new courier details. In the meantime, when needing to book a pickup, please email **ctc.translationalres@sydney.edu.au** and cc in the EVOLUTION study team, who will assist you in organising this.

EVOLUTION key contacts

- **Clinical trial operations, CTC E:** evolution.study@sydney.edu.au
- **Coordinating PI: Shahneen Sandhu E:** shahneen.sandhu@petermac.org
- **Sponsor queries (payments, contracts) E:** trials@anzup.org.au
- **Trial information:** https://anzup.org.au/clinical-trial/evolution/