ANZUP 1603

ANZUP Cancer Trials Group Limited

TheraP Trial News

www.anzup.org.au

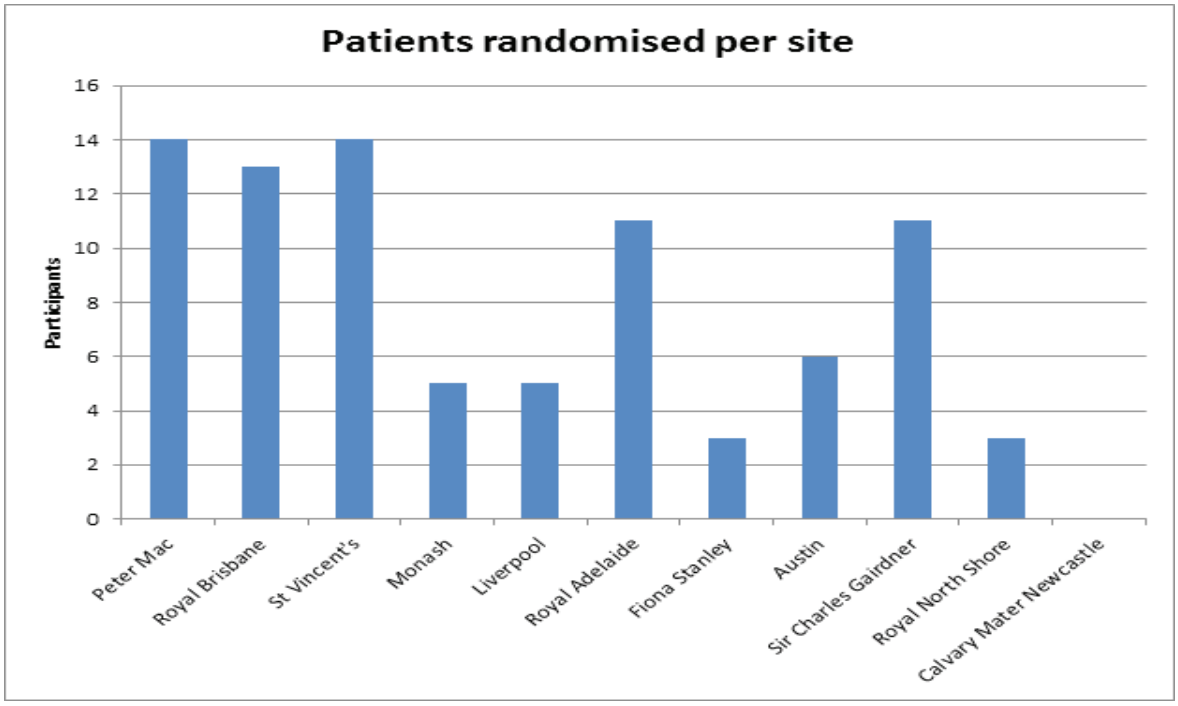
Welcome to our third TheraP newsletter

All eleven sites are now open to recruitment and we have just met the 40% recruitment mark! Thank you to everyone involved in getting all sites activated and on the excellent recruitment so far.

Special congratulations to the teams at St Vincent's and Peter MacCallum who remain in the lead, each with 14 patients randomised.

Welcome to Calvary Mater Hospital - Newcastle who have just joined the study.

Study Update



83 patients randomised

- 41 Lu-PSMA patients
- 44 Cabazitaxel patients

42 (33%) screen failed patients on FDG/ PSMA-PET

Suspension of LuPSMA in Exceptional Responders

'Exceptional response' is defined on the 24- hour post therapy SPECT/CT as marked reduction in uptake at all sites of disease with minimally-avid or non PMSA-avid. Any local assessments of 'exceptional response' need to be confirmed by central review.

NUCLEAR MEDICINE DOCUMENTATION

All trial data must be verifiable by source documentation.

This includes maintaining complete and current Nuclear Medicine documentation.

Nuclear Medicine Manual

Please ensure that the following are filed in your Nuclear Medicine Manual:

- Lutetium Certificates of Analysis – for every trial patient Lu-PSMA dose
- PSMA-11 and PSMA-617 Certificates of Analysis – for every batch used for a trial patient dose
- Ga-PSMA Synthesis & QC worksheets – for every trial patient Ga-PSMA dose
- Lu-PSMA Synthesis & QC worksheets – for every trial patient Lu-PSMA dose

Accountability logs

The following three accountability logs are located in section 8 of your Nuclear Medicine Manual and must document the receipt, administration and/or destruction of ***every*** trial dose:

- Lutetium accountability log
- PSMA-617 accountability log
- PSMA-11 accountability log

Medical record documentation

Details of every dose should be thoroughly documented in the patient medical record, including:

- Date and time of dose
- Dose administered
- Residual activity
- Batch

If you have standard site worksheets which detail all the required information, then this is acceptable. Please ensure that these worksheets are filed with the patient files or in the Nuclear Medicine Manual, as applicable.

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PROTOCOL UPDATE

The first TheraP protocol amendment has recently received HREC approval.

The amendment introduces 6-monthly follow up of patients who are deemed ineligible on screening PET scans. Follow up data should be collected by medical record review, followed by contact to the treating oncologist, and only then to the patient if necessary. A new eCRF form will be available in InForm shortly for these follow ups.

By following up the PET screen-failed patients, we hope to gain further insight into the influence of low PSMA avidity and discordant FDG-avid disease on patient responses to cabazitaxel and Lu-PSMA.

- Patients previously screen failed on the basis of the PET scans will need to be re-consented onto the new Ineligible patient PICF before 6-monthly follow ups can commence
- Newly consenting patients should be consented onto the updated main PICF (Master v2.1)
- Randomised patients do **not** need to be re-consented to the new PICF

For full details of the protocol amendment, please see the attached tracked and clean versions. Please liaise with your Study Coordinator to confirm when local approval has been obtained and the changes can be implemented.

ANSTO Christmas/ New Year Lutetium availability

ANSTO have confirmed that Lutetium will be available for trial patients for the weeks commencing 24th December and 31st December, although no deliveries will be made Christmas Day, Boxing Day or New Years Day.

For deliveries in the week commencing 31st December, the order cut-off is one week early at 10am on Thursday 13th December.

Please don't hesitate to contact us on the trial mailbox or by phone should you have any questions

TheraP is a partnership between ANZUP and the Prostate Cancer Foundation of Australia (PCFA).

Prostate Cancer Foundation of Australia

ANZUP is collaborating with NHMRC CTC to conduct the TheraP study.

NHMRC Clinical Trials Centre

Funding and support for TheraP is provided by:

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TheraP key contacts

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Trial pages: https://www.ctc.usyd.edu.au/our-research/clinical-trials/trial-pages-login.aspx (log in required) here you will find downloadable copies of all study documents and tools.

ANZUP ClinTrial Refer app available for download from iTunes and Google Play