ARTnet Trials Update October 2019

Australasian Radiopharmaceutical Trials network

ARTnet CLINICAL TRIALS UPDATE

ProPSMA Study: a prospective randomised multi-centre study of the impact of Ga-68 PSMA-PET/CT imaging for staging high risk prostate cancer prior to curative-intent surgery or radiotherapy (funded by the Prostate Cancer Foundation of Australia and Movember)

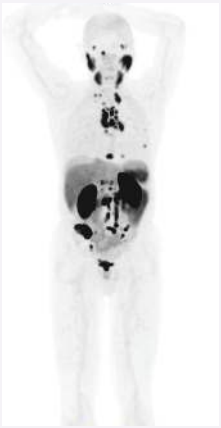
Principal Investigator: Prof Michael Hofman (Peter MacCallum Cancer Centre, Melbourne)

ProPSMA study involved 10 sites across Australia. Prior to patient enrolment, study sites were certified by ARTnet for camera validation for Gallium-68 (see publication below) and for radiopharmaceutical synthesis of Ga-68 PSMA-11. Randomisation of 300 patients for ProPSMA was completed in November 2018, well ahead of schedule, as seen in the accrual chart. This landmark phase 3 randomised trial may lead to global practice changing data by comparing Ga-68 PSMA-11 directly to conventional imaging. All patients have now reached the 6 month follow-up primary endpoint. Sites are now working actively to finalise their data and the analysis of the primary endpoint will be performed shortly. We look forward to the results being presented in the first quarter of 2020.

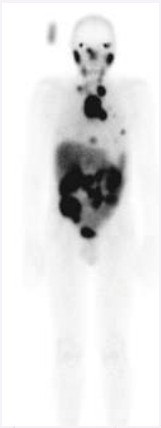
TheraP Study: A randomised phase 2 trial of 177Lu-PSMA617 theranostic versus cabazitaxel in progressive metastatic castration resistant prostate cancer (ANZUP / PCFA / Endocyte / ANSTO / Movember)

Principal Investigator: Prof Michael Hofman (Peter MacCallum Cancer Centre, Melbourne)

TheraP trial involves 11 sites across Australia. ARTnet provided oversite of the Nuclear Medicine manual, and site accreditation for PET camera validation and for radiopharmaceutical synthesis of Ga-68 PSMA and Lu-177 PSMA-617. Recruitment also has progressed extremely well in the TheraP trial, with recent notification that the accrual target of 200 randomised patients has been



Ga68 PSMA PET



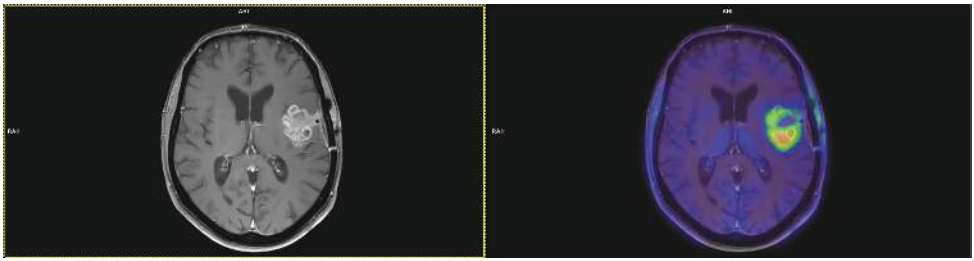
Lu177 PSMA

achieved in Sept 2019, which is 5 months ahead of schedule. All patients had baseline Ga-68 PSMA and F-18 FDG PET/CT scans which were centrally reviewed using the WIDEN system. This first-in-field trial directly compares Lu-PSMA theranostics to cabazitaxel chemotherapy. In the Lu-PSMA arm, patients receive up to 6 cycles of treatment, 6 weekly. Patients are currently completing their scheduled therapy. We anticipate presenting results in mid 2020.

FET PET IN GLIOMA (FIG) STUDY: Prospective multi-centre trial evaluating FET-PET in glioblastoma (TROG/COGNO/ARTnet)

Principal Investigators: Prof Andrew Scott, Austin Health, Melbourne
Dr Eng-Siew Koh, Liverpool Hospital, Sydney

The FIG trial protocol is now fully developed, and the study is in submission to ethics. This study of 210 patients will involve 10 sites across Australia, and will prospectively assess the role of FET PET in detection of suspected recurrence of high grade glioma following therapy, as well as ascertaining the impact of FET PET on radiotherapy planning. ARTnet will provide site certification of PET camera validation and certification of FET radiopharmaceutical synthesis.



PUBLICATIONS

The impact of 68Ga-PSMA PET/CT on management intent in prostate cancer: results of an Australian prospective multicenter study. Paul J Roach, Roslyn Francis, Louise Emmett, Edward Hsiao, Andrew Kneebone, George Hruby, Thomas Eade, Quoc Nguyen, Ben Thompson, Tom Cusick, Michael McCarthy, Colin Tang, Bao Ho, Philip Stricker, and Andrew Scott. J Nucl Med 2018 59:82-88.

Accuracy of Dose Calibrators for 68Ga PET Imaging: Unexpected Findings in a Multicenter Clinical Pretrial Assessment. Dale L. Bailey, Michael S. Hofman, Nicholas J. Forwood, Graeme J. O'Keefe, Andrew M. Scott, Winifred M. van Wyngaardt, Bonnie Howe, Olga Kovacev, and Roslyn J. Francis; on behalf of ARTnet and the ProPSMA Trial Investigators. J Nucl Med 2018; 59:636–638.

A prospective randomized multicentre study of the impact of gallium-68 prostate-specific membrane antigen (PSMA) PET/CT imaging for staging high-risk prostate cancer prior to curative-intent surgery or radiotherapy (proPSMA study): clinical trial protocol. Michael S. Hofman, Declan G. Murphy, Scott G. Williams, Tatenda Nzenza, Alan Herschtal, Richard De Abreu Lourenco, Dale L. Bailey, Ray Budd, Rodney J. Hicks, Roslyn J. Francis and Nathan Lawrentschuk. BJU Int. 2018 Nov;122(5):783-793.

For further Information visit
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