

ANZUP – A NEW CO-OPERATIVE CANCER TRIALS GROUP IN GENITO-URINARY ONCOLOGY

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Introduction

The Australian and New Zealand Urogenital and Prostate (ANZUP) Cancer Trials group was formed in 2008 as the first comprehensive co-operative trials group for genito-urinary oncology in Australia and New Zealand, by the merger of the Australian Prostate and Urogenital cancer Group (APUG) and the Australian and New Zealand Germ Cell Trials group (ANZGCTG), with funding from The Victorian Cancer Agency and subsequently from Cancer Australia. ANZUP's stated mission is to conduct clinical trial research to improve treatment of bladder, kidney, testicular and prostate cancers (<http://www.anzup.org.au> *). To this end, it aims to bring together all the professional disciplines and groups involved in researching and treating urogenital cancers.

ANZUP's multidisciplinary membership, in excess of 750 as at June 2014, continues to grow. In order to help its members improve the care of their patients, ANZUP also serves an important educational purpose, primarily through its Annual Scientific Meeting, which also includes a Community Forum and a multidisciplinary Masterclass aimed at clinicians, allied health practitioners and researchers.

The Scientific Advisory Committee which drives ANZUP research efforts, is organized into disease-specific subcommittees for prostate, bladder (urothelial), renal and germ-cell cancer; and non-disease-specific subcommittees for Correlative & Translational Research and Quality Of Life &

Supportive Care, as well as a Consumer Advisory Panel. ANZUP collaborates with the NHMRC Clinical Trials Centre at the University of Sydney for the conduct of many of its trials.

A number of factors have been key to ANZUP's success to date. ANZUP met a perceived need within the clinical and research community for a group in Australia and New Zealand dedicated to all genitourinary cancers and all disciplines – this has led to a rapidly growing membership, ANZUP's productivity depends on broad multi-disciplinary engagement, the generous contributions of time and expertise by its members as well as streamlined and effective mechanisms for protocol development and implementation.

Conversely, ANZUP and other Australian cooperative cancer clinical trials groups (CCTG) face challenges that differ from those of groups in other regions. Australian CCTGs are separate entities, not subcommittees or subgroups of one larger overarching organization. This results in some duplication of infrastructure, however it also removes the risk of dilution of resources that might come to a single group. Many Australian CCTGs receive infrastructure funding from the Australian Government through Cancer Australia. However, these funds cannot be used for project operations and each project must seek and secure adequate funding before they can proceed. Centralised ethics review processes have now been established across many Australian states, but there is still the risk that issues of local research governance can slow down processes of trial approval and activation.

Summary of Trials

In the first five years of its existence, ANZUP has already established an extensive portfolio of completed and accruing trials (additional detail and updates available at <http://www.anzup.org.au/content.aspx?page=trials>).

Germ cell: A single-arm phase II trial of an accelerated regimen of bleomycin, etoposide and cisplatin has shown promising efficacy in metastatic germ cell tumours[1] and led to the subsequent development and funding of a randomized phase III trial, currently accruing. ANZUP has also completed accruing to a study of cognitive changes resulting from chemotherapy (<https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?id=83815>), and published on current patterns of care for stage I disease[2] and quality of life improvements from a novel anti-emetic schedule used during cisplatin based chemotherapy.[3] ANZUP partnered with the Psycho-oncology Co-operative Research Group (PoCoG) in a cross-sectional study of survivors of testicular cancer which identified a number of psychological and sexual unmet needs,[4] leading to the development of a novel internet-based intervention currently being piloted in 4 Australian centres.

Renal: ANZUP was a key international collaborator with the UK Medical Research Council on the SORCE trial

(http://www.ctu.mrc.ac.uk/research_areas/study_details.aspx?s=31), a randomized phase III trial of adjuvant sorafenib (1 or 3 years) vs placebo for high-risk resected renal cell carcinoma, for which ANZUP recruited around 10% of the 1658 participants. ANZUP investigators also conceived, developed and led a substudy within the SORCE trial to determine the benefits participants and their doctor judged necessary to make the side effects and inconvenience of adjuvant sorafenib worthwhile. This substudy included participants from all centres in ANZ and several in the UK. Many ANZUP sites also participated in the TRANSORCE tissue and blood collection substudy.

ANZUP has also developed and completed accrual to the phase II EVERSUN trial of alternating everolimus and sunitinib as first line therapy for metastatic renal cell carcinoma (<http://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?ACTRN=12609000643279>). EVERSUN also included the EVERSUN-T substudy of circulating tumour cells and soluble biomarkers, illustrating ANZUP's commitment to incorporating translational research whenever possible into its clinical protocols.

Prostate: ANZUP has partnered with the Trans-Tasman Radiation Oncology Group (TROG) and the Urological Society of Australia and New Zealand (USANZ) to help conduct the RAVES trial, a phase III randomized study of radiation adjuvant vs early salvage after radical prostatectomy for prostate cancer with extra-prostatic extension or positive surgical margins (<http://clinicaltrials.gov/ct2/show/NCT00860652>). Procure,[5] a collaborative

study between ANZUP and the Primary Care Collaborative Cancer Clinical Trials Group (PC4) (a general practice study group) of a shared care model for prostate cancer patients, has completed accrual and is in follow-up.

Ongoing ANZUP studies for prostate cancer patients include a phase II randomized trial of a mindfulness-based cognitive therapy group intervention[6] for men with advanced disease (in collaboration with Griffith University and Cancer Council Queensland) and a mixed methods exploratory study of sexual well-being and quality of life in men and their partners (in collaboration with the University of Western Sydney).

ANZUP has also recently developed and activated two international collaborative studies of enzalutamide for androgen deprivation in men with prostate cancer. ENZARAD is a phase III randomized trial in men undergoing external beam radiotherapy for high-risk localized disease (<http://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?id=365611>).

ENZAMET is a phase III randomized trial of first line therapy for men with hormone-naïve metastatic disease (<http://www.australianclinicaltrials.gov.au/node/1510>).

Bladder: For patients with high-risk non-muscle invasive bladder cancer, ANZUP has developed and opened a phase III randomized trial comparing a combination induction and maintenance regimen of intravesical BCG and Mitomycin to BCG alone (<http://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?id=364165>).

Conclusion

As outlined above, ANZUP has established a strong track record in the development, initiation, conduct and reporting of multicenter clinical trials in genito-urinary oncology. It has already put in place significant collaborative partnerships, including extensive international links that are bearing fruit in terms of contributions from Australia and New Zealand to trials led by other groups, as well as engagement of international groups in ANZUP-led trials.

This network of cooperation and collaboration can only lead to more effective and timely investigator-led clinical research and to improved patient outcomes.

*All websites referenced accessed on 10th June, 2014.

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Conflicts of Interest

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