

# Abstract #394646: Trial in Progress – Primary retroperitoneal lymph node dissection for clinical stage II testicular germ cell tumour and its impact on health-related quality of life compared to chemotherapy or radiotherapy (PRESTIGE)

Ciara Conduit<sup>1,2,3</sup>, Jeremy Lewin<sup>1,2,4</sup>, Elizabeth C Liow<sup>3,5</sup>, Haryana Dhillon<sup>6,7</sup>, Wei Hong<sup>3</sup>, Richard De Abreu Lourenco<sup>8</sup>, Nathan Lawrentschuk<sup>9,10</sup>, Benjamin Thomas<sup>10</sup>, Peter Grimison<sup>11,12</sup>, Shomik Sengupta<sup>13</sup>, Ben Tran<sup>1,2,3,14</sup>.

<sup>1</sup>Medical Oncology, Peter MacCallum Cancer Centre, <sup>2</sup>Sir Peter MacCallum Department of Oncology, The University of Melbourne, <sup>3</sup>Walter and Eliza Hall Institute of Medical Research, <sup>4</sup>ONTrac at Peter Mac, Victorian Adolescent and Young Adult Cancer Service, <sup>5</sup>Medical Oncology, Monash Health, <sup>6</sup>Centre for Medical Psychology and Evidence-Based Decision-Making, School of Psychology, Faculty of Science, The University of Sydney, <sup>7</sup>Psycho-Oncology Cooperative Research Group, School of Psychology, Faculty of Science, The University of Sydney, <sup>8</sup> Centre for Health Economics Research and Evaluation, University of Technology Sydney, <sup>9</sup>Urology, Peter MacCallum Cancer Centre, <sup>10</sup>Surgery, Royal Melbourne Hospital, University of Melbourne, <sup>11</sup>Medical Oncology, Chris O'Brien Lifehouse, <sup>12</sup>School of Medicine, University of Sydney, <sup>13</sup>Urology, Eastern Health, <sup>14</sup>Epworth Healthcare.

## Background

- There is a growing lens on the quality of survivorship of survivors of testicular germ cell tumours (TGCT).
- Retroperitoneal lymph node dissection (RPLND) is increasingly used as primary treatment for non-seminomatous germ cell tumours (NSGCT) and is emerging as a safe alternative for selected patients with seminoma in order to avoid potential toxicities associated with chemotherapy.
- There is growing evidence to support the role of microribonucleic (miR) acids as a biomarker in TGCT including as a marker of residual disease and detection of relapse.

## Methods

- PRESTIGE is a prospective cohort study **in progress**.
- Funding: Below the Belt Research Fund grant (supported by the Australian and New Zealand Urogenital and Prostate [ANZUP] Cancer Trials Group).
- Sponsor: Peter MacCallum Cancer Centre (PMCC).
- Human Research Ethics Committee: PMCC.
- Coordinating centre: Walter and Eliza Hall Institute of Medical Research.
- Endorsed by ANZUP Scientific Advisory Committee.

## Trial Endpoints

- Primary outcome:** Global Health Status over 24 months.  
**Secondary outcomes:**
2. Health-related quality of life (HRQoL) over 24 months by treatment cohort evaluated using:
    - EORTC-QLQ-C30
    - EORTC-QLQ-TC26
    - Brief Male Sexual Function Inventory
    - Custom-made questionnaires re: fertility and retrograde ejaculation.
  3. Patterns of recurrence.
  4. Complications, including retrograde ejaculation and fertility concerns.
  5. Progression-free and overall survival following RPLND.
  6. Positive predictive value of miR-371 for recurrence.
  7. Health care resource utilisation.
  8. Optional semi-structured interview exploring survivorship issues.

## Interventions

- Treatment recommended by MDT addressing >10 RPLND/year and >20 advanced TGCT/year; treatment administered in accordance with standard of care.
- Serum and plasma miR-371 in RPLND cohort.
- Questionnaires and data collection administered by the Australian testicular cancer registry, iTestis:



Example custom-made questions to evaluate retrograde ejaculation:

- "Have you been able to climax?"
- "When you have climaxed, did you ejaculate?"
- "If not, how much of a concern was this?"

Example custom-made questions to evaluate fertility concerns:

- "Do you have any concerns about your fertility?"
- "Have you tried to conceive a pregnancy since your cancer diagnosis?"
- "Have you successfully conceived a pregnancy since your cancer diagnosis? If you did conceive, were there any issues in relation to getting pregnant?"

## Recruitment progress

- Target: 120 participants, including 30 having RPLND, 60 chemotherapy and 30 radiotherapy.
- 2/3 planned sites open and recruiting since August 2022.

**We hypothesise that primary RPLND will have less detrimental impact on HRQoL with comparable oncological outcomes compared to chemotherapy and radiotherapy.**

