RAVES TRIAL

Trial Title: A Phase III Multi-centre Randomised Trial Comparing Adjuvant Radiotherapy (RT) With Early Salvage RT in Patients With Positive Margins or Extraprostatic Disease Following Radical Prostatectomy.

Trial Acronym: RAVES — Radiotherapy - Adjuvant Versus Early Salvage

Protocol Number: TROG 08.03

Trial Design: Randomized phase III open-label multi-centre clinical trial

Collaborators: Trans-Tasman Radiation Oncology Group (TROG) Urological Society of Australia and New Zealand (USANZ)

ANZ Study Chairs: Dr. Maria Pearse & Dr. Andrew Kneebone

ANZ Coordinating Centre: TROG Trial Centre, Auckland City Hospital

Trial Coordinator: Ms. Carol Fraser-Browne

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Patient Population: Males aged 18 years and over with prior radical prostatectomy (RP) for adenocarcinoma of the prostate.

Intervention:
Arm 1: Experimental Adjuvant Radiotherapy
Radiation: Adjuvant radiation Therapy
Adjuvant RT (ART) commenced within 4 months of RP. 64Gy in 32 fractions to the prostate bed.

Arm 2: Experimental Active Surveillance with Early Salvage Radiotherapy
Radiation: Early Salvage Radiotherapy
Active surveillance with early salvage RT (SRT). 64Gy in 32 fractions to the prostate bed. The trigger for SRT is PSA level ≥ 0.2ng/ml. RT should commence as soon as possible (no later than 4 months) following the first PSA measurement ≥ 0.2ng/mL.

Primary Outcome: The primary aim of the trial is to test the hypothesis that surveillance with early salvage RT results in equivalent biochemical control and improved quality of life (QoL) when compared with adjuvant RT.

Secondary Outcomes: Quality of Life
Toxicity
Anxiety/Depression
Biochemical failure-free survival
Overall survival
Disease-specific survival
Time to distant failure
Time to local failure
Time to the initiation of androgen ablation
Quality adjusted life years
Cost-utility

Status: Active and Recruiting