1. Background

There is impetus to identify biomarkers in testicular germ cell tumours (TGCT) to help select those at high-risk of relapse following orchiectomy and target interventions to prevent over-treatment. miR-371 has been shown to reliably predict presence of active malignancy over and above currently available biomarkers. More clinical evidence is required to ascertain its clinical utility as a marker of residual disease to guide treatment recommendations in stage 1 TGCT and other settings.

In this ongoing trial, we aim to demonstrate the clinical utility of miR-371 in detecting minimal residual disease in individuals with clinical stage 1 TGCT following orchiectomy.

2. Study Design

Orchidectomy + perioperative staging

Population
- Adults with clinical stage 1 testicular germ cell tumour (seminoma OR non-seminoma).
- Consent within 6 weeks of Orchidectomy.
- Planned for active surveillance without adjuvant treatment.

Clinical data: Administered by Australia’s testicular cancer registry, iTestis. Biospecimen tracking: REDCap.

Sample type: At defined timepoints during follow-up, serum, plasma and buffy coat will be collected to perform miR-371 analysis using quantitative PCR technology. Archival tissue from diagnosis ± relapse is identified for future translational research.

3. Methods

Clinical data: Administered by Australia’s testicular cancer registry, iTestis. Biospecimen tracking: REDCap.

Sample type: At defined timepoints during follow-up, serum, plasma and buffy coat will be collected to perform miR-371 analysis using quantitative PCR technology. Archival tissue from diagnosis ± relapse is identified for future translational research.

4. Study Progress

- Recruitment commenced February 2022.
- 11/12 sites actively recruiting in Australian and New Zealand.

Primary Outcome
12-month relapse free-survival in post-orchiectomy miR-371-positive and -negative populations.

Secondary Outcomes
- miR-371 elevation at time of clinically-confirmed relapse.
- Change in miR-371 during active surveillance and at time of relapse.
- Interaction between cost and clinically-confirmed relapse.
- Contribution of patient-level data to joint analysis of COG AGCT1531 and SWOG 1823.

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