

# CLIMATE Trial News

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## Welcome to the first CLIMATE newsletter

We currently have 3 sites open and recruiting, with RGO in progress at the remaining 8 sites across NSW, Victoria and Queensland. So far we have 13 patients recruited for the planned 200 in total: 9 recruited at Epworth by Site PI and Study Chair Ben Tran, and 4 at PeterMac by Site PI Jeremy Lewin. Congratulations!

*Please note anyone with stage 1 testicular cancer is eligible for the CLIMATE study.*

## A message from Study Chair: Associate Professor Ben Tran

"Testicular cancer is a highly curable disease, but many patients are over treated or over investigated unnecessarily, which can result in long term morbidity and increased anxiety. CLIMATE aims to assess the clinical utility of the exciting new biomarker miR-371 in stage 1 testicular cancer. We are hoping to demonstrate that miR-371 can better identify patients who may need adjuvant chemotherapy and those who can have less frequent surveillance. This would maximise outcomes while minimising treatment in this young population."



## Study team introduction

**Study Chair:** Associate Professor Ben Tran  
Deputy Study Chair: Dr Ciara Conduit

### **ANZUP Team (study sponsor):**

Chair: Ian Davis  
CEO: Marg McJannett  
Head of Research: Nisha Rana  
Clinical Trials Team: Thomas Cusick, Antoinette Fontela & Eugenie Lee

### **Walter and Eliza Hall Team (coordinating centre):**

Clinical Lead: Ben Tran  
Project Managers: Kristina Zlatic and Sophie O'Haire  
Statistician: Wei Hong  
Ethics and Governance: Evelyn Yip and Kristen Kiratzis

### **Contact us:**

Key Contacts: [CLIMATE@mh.org.au](mailto:CLIMATE@mh.org.au), which is the trial mailbox for all your study related questions or [trials@anzup.org.au](mailto:trials@anzup.org.au) for any sponsor related queries.

## What is CLIMATE?

CLIMATE is a prospective, single arm, non-interventional, cohort study assessing the Clinical utility of miR-371a-3p as a marker of residual disease in Clinical Stage 1 Testicular Germ Cell Tumour, following orchidectomy.

## Background:

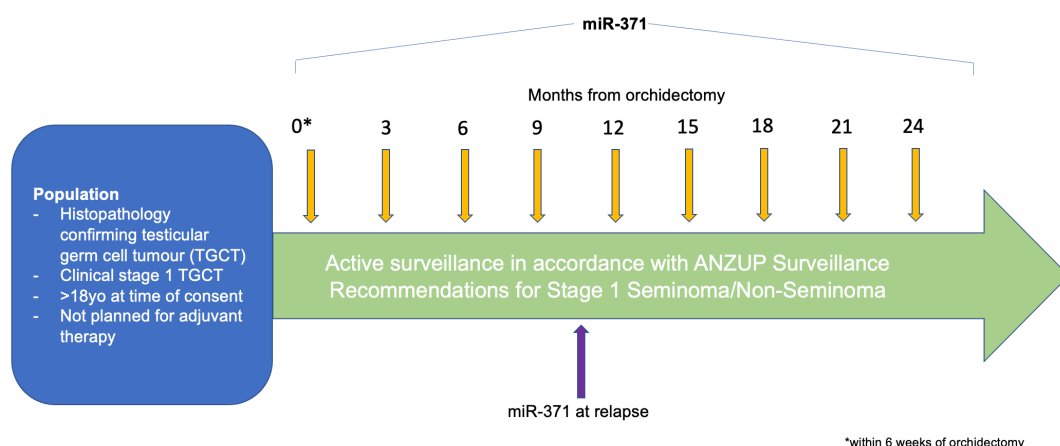
Following orchidectomy, most people with clinical stage I testicular cancer will be cured, however up to 20% of patients with seminoma and ~30% of those with non-seminoma will relapse and go onto require further treatment. There is impetus to improve biomarkers to help identify individuals at high-risk of relapse following stage 1 testicular cancer and target interventions to this group. miR-371 expression has been clearly shown to reliably predict presence of active malignancy over and above currently available biomarkers. Prospective clinical evidence is needed to understand the potential clinical utility of this biomarker. CLIMATE aims to demonstrate the clinical utility of miR-371 in detecting minimal residual disease in stage 1 testicular germ cell tumours following orchidectomy.

## Brief eligibility:

- Inclusion
  - Adults with recent diagnosis of histologically confirmed testicular germ cell tumour
  - Clinical stage 1 disease planned for active surveillance without adjuvant chemotherapy
- Exclusion
  - No evidence of advanced/metastatic disease or extragonadal primary site
  - Previous history of testicular germ cell tumour

## Study activities

All patients enrolled to the study will undergo active surveillance in accordance with the Australian and New Zealand Urogenital and Prostate (ANZUP) Cancer Trials Group's surveillance recommendations for clinical stage 1 seminoma or non-seminomatous germ cell tumours. In addition, patients will have clinical and outcome data, and blood sampling for miR-371 performed every three months (and at relapse) for 24 months following orchidectomy. Clinical data for this study will be collected using the established iTestis registry. miR-371 testing will be performed by Nexomics.



## CLIMATE key contacts

- Clinical trial operations, E: [CLIMATE@mh.org.au](mailto:CLIMATE@mh.org.au)
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- Trial information: <https://anzup.org.au/clinical-trial/climate/>