

# CLIMATE Trial News

[www.anzup.org.au](http://www.anzup.org.au)

## Welcome to the second CLIMATE newsletter

CLIMATE has been busy over the last few months with seven sites open and recruiting, and the remaining four sites progressing through RGO. We have now recruited almost 15% of the target (28/200) and anticipate we will continue to recruit rapidly as more sites become active.

Congratulations to all involved!!

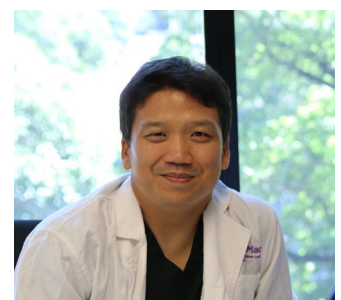
*Please note anyone with stage 1 testicular cancer is eligible for the CLIMATE study.*

## Study accrual:

Site	PI	Participants recruited
<b><i>Open for recruitment</i></b>		
Epworth Freemasons (VIC)	Ben Tran	16
Peter Mac (VIC)	Jeremy Lewin	11
Calvary Mater Newcastle (NSW)	James Lynam	1
Austin Hospital (VIC)	Andrew Weickhardt	0
Eastern Health Box Hill (VIC)	Phillip Parente	0
Barwon Health Geelong (VIC)	David Campbell	0
Chris O'Brien Lifehouse (NSW)	Peter Grimison	0
<b><i>Not yet activated</i></b>		
Royal Brisbane and Women's Hospital (QLD)	Anna Kuchel	N/A
Princess Alexandra Hospital (QLD)	Aaron Hansen	
Sydney Adventist Hospital (NSW)	Gavin Marx	
St Vincent's Hospital Sydney (NSW)	Ben Namdarian	

## Study Chair: Associate Professor Ben Tran

*"The study is not overly onerous, however does require the engagement of local urologists to ensure that referrals come within a timely manner."*



## New Protocol Amendment (version 3):

You may have heard that we recently submitted a minor amendment, which was approved last week. The rationale for the changes was based upon the experiences of recruiting sites who found that the windows for miRNA collection within the first 12 months were tight and inflexible for an often, highly mobile population. The latest, HREC-approved protocol now permits a +/- 14-day window for miRNA at all time points, including <12 months post-orchidectomy, where +/-7 days was previously stipulated.

We have additionally altered the wording relating to surveillance to clarify that adherence to the ANZUP Surveillance Recommendations is recommended, but not mandated per protocol. This will provide flexibility in follow-up (at clinician discretion) where routine surveillance visits and miRNA sampling timepoints don't meet. In turn, hopefully, this will be less burdensome for participants who are generously providing their time to be involved in the study.

Please let us know if you have any queries about these changes and our team will be in touch soon for how this may impact your site.

## Screening:

Please continue to screen potential participants who may be eligible for the study:

- Adults with clinical stage 1, testicular germ cell tumour (seminoma *and* non-seminoma)
- Orchidectomy within 6 weeks prior to consent (and baseline miRNA sample)
- Planned for active surveillance following orchidectomy (adjuvant therapy *not* permitted)
- No prior history of testicular cancer

## Tips and Tricks

- Please discuss CLIMATE with your local surgical colleagues and MDTs. Several potential participants have been referred >6 weeks post-orchidectomy and therefore are ineligible for the study.
- For activated sites, please keep a log in the event of any protocol deviations.
- Adding in surveillance visit detail onto iTestis contemporaneously with the patient's routine review should take ~1 minute.
- At routine visits where miRNA sampling is required, depending on your local set-up, your site may find it easier to collect any standard-of-care bloods at the same time and spare the participant >1 venepuncture.

## New Schedule of Assessments (post-amendment) at your site

Assessment	Screening	Study period									
		Month 3 post-orch	Month 6 post-orch	Month 9 post-orch	Month 12 post-orch	Month 15 post-orch	Month 18 post-orch	Month 21 post-orch	Month 24 post-orch	Relapse	
<i>+/-14 days window for all time points</i>											
Written informed consent	X										
Routine imaging confirming stage 1 testicular cancer*	X										
Clinical and outcome data entered into iTestis	X	X	X	X	X	X	X	X	X	X	
miRNA blood collection	X	X	X	X	X	X	X	X	X	X	
Routine surveillance**		X									
Optional collection of paraffin-embedded tumour samples	X										

\*Routine imaging confirming stage 1 testicular cancer should be performed within 14 days prior to orchidectomy, or within 6 weeks following orchidectomy; there is no requirement to repeat imaging at consent if already performed within these windows.

\*\*See <https://anzup.org.au/recommendations-and-resources/> for ANZUP Surveillance Recommendations; time points may vary from above. All routine visits should also be entered into iTestis.

### CLIMATE key contacts

- Clinical trial operations (WEHI) to Sophie O’Haire and Kristina Zlatic, E: [CLIMATE@mh.org.au](mailto:CLIMATE@mh.org.au)
- Coordinating PI: Ben Tran E: [ben.tran@petermac.org](mailto:ben.tran@petermac.org)
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- Trial information: <https://anzup.org.au/clinical-trial/climate/>