

CLIMATE Trial News

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Welcome to the third CLIMATE newsletter

CLIMATE has started the year off well with nine sites open and recruiting. We have now recruited over 25% (54/200) and anticipate we will continue to recruit rapidly as more sites get into the process of recruiting.

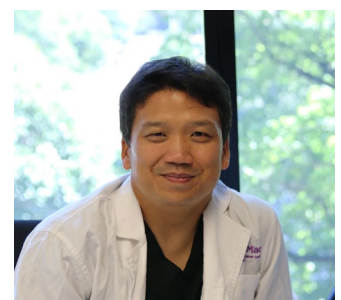
Congratulations to all involved!

Study accrual:

Site	PI	Participants recruited
<i>Open for recruitment</i>		
Epworth Freemasons (VIC)	Jeremy Lewin	23
Peter Mac (VIC)	Ben Tran	19
Calvary Mater Newcastle (NSW)	James Lynam	3
Austin Hospital (VIC)	Andrew Weickhardt	1
Eastern Health Box Hill (VIC)	Phillip Parente	2
Barwon Health Geelong (VIC)	David Campbell	0
Chris O'Brien Lifehouse (NSW)	Peter Grimison	2
Princess Alexandra Hospital (QLD)	Aaron Hansen	5
Sydney Adventist Hospital (NSW)	Gavin Marx	0
St Vincent's Hospital Sydney (NSW)	Ben Namdarian	0
<i>Not yet activated</i>		
Royal Brisbane and Women's Hospital (QLD)	Anna Kuchel	N/A
Te Whatu Ora Southern (NZ)	Orlaith Heron	N/A

Study Chair: Associate Professor Ben Tran

"miR371 is gaining momentum with recent presentations at GU ASCO and likely further data at ASCO. It is great for ANZUP to contribute to the growing data that may help miR371 become a standard of care test in the future."



ASCO 2023:

CLIMATE study Trial In Progress (TiP) abstract has been selected for poster presentation at the 2023 ASCO Annual Meeting taking place in Chicago, Illinois. Thank you for all your input on the abstract submission.

Study Management Committee:

Upcoming Study Management Committee (SMC) in May 2023: The study team is planning a (SMC) meeting in May 2023 to discuss the study updates and any questions or concerns regarding the conduct of the study. Look out for the meeting invite.

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)
- Orchiectomy within 6 weeks prior to consent (and baseline miRNA sample)
- Planned for active surveillance following orchiectomy (adjuvant therapy *not* permitted)
- No prior history of testicular cancer

Tips and Tricks

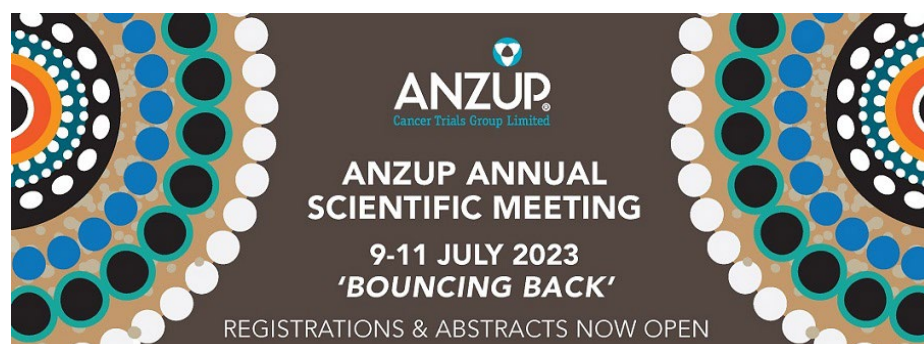
- Please discuss CLIMATE with your local surgical colleagues and MDTs. Several potential participants have been referred >6 weeks post-orchidectomy and therefore are ineligible for the study.
- At routine visits where miRNA sampling is required, depending on your local set-up, your site may find it easier to collect any standard-of-care bloods at the same time and spare the participant >1 venepuncture.
- Please track timepoints for your enrolled patients. Booking in the next review at each blood collection can help forward manage this. The WEHI team will arrange REDCap alerts and keep site supplies updated but we ask sites to keep an eye on this for active patients and get in touch if any issues!
- Make sure to register your patients on REDCap and iTestis as soon as they have consented to allow for alerts and kit supplies to be up to date. This also helps ensure the correct kits/labels are used for sample processing.
- If a patient has a recurrence within their next timepoint window, only a relapse sample is required. Use the relapse 'RL' labels and the next sequential kit for sample collection and enter this sample data in the relapse form in REDCap.

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
- Coordinating PI: Ben Tran E: ben.tran@petermac.org
- Sponsor queries (payments, contracts) Antoinette Fontela E: trials@anzup.org.au
- Trial information: <https://anzup.org.au/clinical-trial/climate/>