

TIGER Trial News

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Welcome to our fourth TIGER newsletter

We'd like to extend our thanks to the principal investigators, co-investigators, study co-ordinators and research teams at all the participating sites for your ongoing commitment and support to the study throughout 2019.

Recruitment update

Global recruitment is currently at 249/420 patients randomised to the trial. Australia has contributed 5 patients to this total in just over 12 months, which is a great achievement in this rare population. Please reach out to colleagues within your state regarding the trial, and encourage cross-referral of suitable patients.

Site	Principal Investigator	Activation Date	Screened	Enrolled
Princess Alexandra Hospital	Euan Walpole	10 Aug 2018	2	1
Box Hill Hospital	Ian Davis	18 Sept 2018	1	1
Chris O'Brien Lifehouse	Peter Grimison	26 Sept 2018	4	2
Peter MacCallum Cancer Care	Guy Toner	31 Oct 2018	1	1
TOTAL			8	5
TARGET RECRUITMENT			60 patients	

What is TIGER?

A Randomised Phase III Trial Comparing Conventional-Dose Chemotherapy Using Paclitaxel, Ifosfamide, and Cisplatin (TIP) with High-Dose Chemotherapy Using Mobilising Paclitaxel plus Ifosfamide Followed by High-Dose Carboplatin and Etoposide (TI-CE) as First Salvage Treatment in Relapsed or Refractory Germ Cell Tumours (ANZUP 1604)
 Current approved protocol: V8.0

TIGER key contacts:

Clinical trial operations:
tiger@ctc.usyd.edu.au

Sponsor queries
 (payments, contracts)
 Nisha Rana:
nisha.rana@anzup.org.au

Please continue to use the randomisation checklist to screen potential patients at your site. If there are any questions regarding a patient's eligibility, please contact the TIGER trials team at tiger@ctc.usyd.edu.au

Audit:

TIGER sites will be audited within 18 months of recruiting the 1st patient at each site. Please ensure that all source and study documents are up to date and concise, and study processes have been adhered to and clearly documented.

Hints and Tips:

1. Investigators and site staff need to ensure their CTEP account is renewed annually. The NHMRC Clinical Trials Centre will send reminders and assist you through this process. Please contact the TIGER mailbox if you have any questions regarding your account.

2. Please note that tumour markers (AFP HCG LDH) are required to be collected on both day 1 and day 15 of protocol chemotherapy, both for Arm A (TIP) cycles 1-4 and Arm B (TI-CE) cycles 3-5. This is detailed in footnote 3 of the study calendar within section 5.0 of the protocol.

ANZUP & CTC Shutdown:

The ANZUP office will be closed from 5.00pm, Friday 20th December 2019 and will re-open on Thursday 2nd January 2020.

The NHMRC Clinical Trials Centre will be closed from 5.00pm, Friday 20th December 2019 and will re-open at 9.00am on Tuesday, 7th January 2020. If you require emergency assistance with a randomisation, registration or to process a SUSAR please phone +61 406 384 367. All other enquiries will be responded to on Tuesday, 7th January 2020.

The TIGER study team would like to wish you a safe and happy holiday season.

We are grateful to the Movember Foundation for their financial support to conduct this study



TIGER is being led by ANZUP Cancer Trials Group in collaboration with the NHMRC CTC.



Alliance for Clinical Trials in Oncology is the Lead Group in the USA.



ANNUAL SCIENTIFIC MEETING
ADELAIDE CONVENTION CENTRE
19-21 JULY 2020

TIGER key contacts

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- Sponsor queries (e.g. site payments, contracts) E: nisha.rana@anzup.org.au T: +61 2 8036 5271
- Coordinating PI: A/Prof Peter Grimison E: peter.grimison@lh.org.au
- Trial information: <https://www.anzup.org.au/content.aspx?page=trials-tiger>