

KEYPAD Trial News

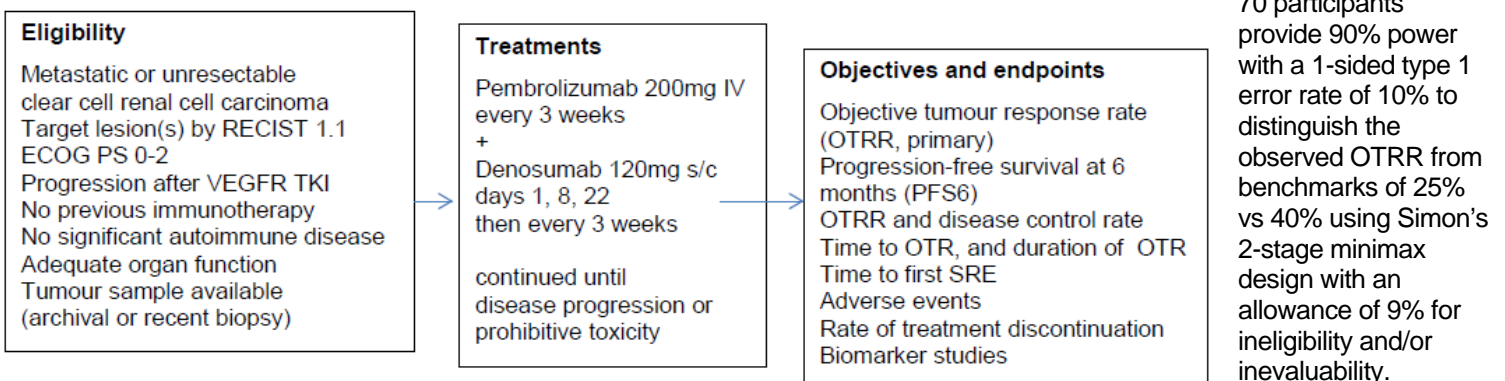
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Welcome to the first KEYPAD newsletter

KEYPAD opened its first sites on 11 December 2017. To date, nine sites are open to recruitment with another four completing activation and local approval processes in the coming weeks. St George Hospital (PI Carole Harris) was first off the rank and has so far recruited three patients. Thank you to Carole, Antoinette and the team. A fourth patient was recruited at Concord Repatriation General Hospital in April.

Initial reports show the patients are responding well and we look forward to seeing this at the first tumour assessment early next month.

KEYPAD Study schema



Current recruitment

Site	Status	Patients
Calvary Mater Newcastle	Open	
St George Hospital	Open	3
Eastern Health / Box Hill	Open	
Royal Brisbane & Women's Hosp.	Open	
Northern Cancer Institute	Open	
Concord Repatriation General Hospital	Open	1
Flinders Medical Centre	Open	
Icon Cancer Care	Open	
Monash Health	Expected Q2 2018	
Peter MacCallum Cancer Centre	Open	
Fiona Stanley Hospital	Expected Q3 2018	
Sunshine Coast University Hosp.	Expected Q3 2018	
Westmead Hospital	Expected Q3 2018	
Total	9 sites open	4

Monthly updates

The following will be requested at the start of the month:

1. Updated screening log. Please provide accurate screen failure reasons to help us trend any barriers to recruitment.
2. Any new (de-identified) CT scan reports taken in the last month.
3. Any new blood collection forms collected in the last month (including both frozen KEYPAD TR and AUTOCHECK samples)
4. Completed Tissue Availability Forms (Appendix B of the biospecimen sampling manual) – at least one per patient.

Please send scanned, de-identified copies of the above to keypad@ctc.usyd.edu.au.

KEYPAD is a collaboration between ANZUP and CTC



PI spotlight: Medical Oncologist Carole Harris

Carole Harris is a medical oncologist based at St George and Sutherland Hospitals with a keen interest in GU cancers and clinical trials. She is an active member of the ANZUP Renal Cell Subcommittee.

Carole is the first to recruit to KEYPAD at St George Hospital. St George is a 627 bed tertiary hospital in southern Sydney with a large clinical trial unit. Carole says the hospital's kidney MDT allows eligible patients for clinical trials to be easily identified.



Patient tissue for KEYPAD

KEYPAD translational studies are critical to the outcomes of the trial. KEYPAD translational research aims to examine the associations between clinical outcomes and possible prognostic and/or predictive biomarkers (tissue and circulating) related to immune and RANK signalling. To do this, adequate tissue samples are essential. **Only patients with a suitable tumour specimen can be enrolled in the KEYPAD trial.**

At screening

Email the following to keypad@ctc.usyd.edu.au:

1. 'KEYPAD Confirmation of Tissue Availability Form' (Appendix B of the biospecimen sampling manual), completed and signed by the pathologist
2. Copy of the de-identified pathology report.

During the course of the trial

1. Request and hold the tissue block at site until shipping notification is received from KEYPAD TR team OR
2. Request tissue when advised by the KEYPAD TR team. NB: Slides must not be cut until the tissue is requested to ensure the quality of the tissue
3. Use the participant trial number as the identifier on the tissue samples.

AUTO-CHECK blood samples

The AUTO-CHECK sub-study <http://gccti.org.au/studies> is included in KEYPAD (and 5 other CTC trials of immunotherapies in other tumours). AUTO-CHECK aims to determine if genetic susceptibility to autoimmunity contributes significantly to immune related adverse events (IRAEs) after treatment with immune checkpoint inhibitors.

Bloods for AUTO-CHECK:

1. Are collected at baseline, prior to Cycle 3 and at time of a significant IRAE (should this occur).
2. Must be collected AND shipped (the same day) Mon to Thu only. The exception is for significant IRAE collections on Fri - Sun (see biospecimen sampling manual section 7.6.2 for instructions). Use the pre-filled shipping waybills provided.

If sufficient blood volume cannot be obtained, prioritise collection of KEYPAD bloods over AUTO-CHECK bloods.



ANNUAL SCIENTIFIC MEETING
8-10 JULY 2018
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KEYPAD key contacts

- Clinical trial operations, CTC E: keypad@ctc.usyd.edu.au and kate.ford@ctc.usyd.edu.au
- Sponsor queries (e.g. site payments, contracts) E: simran.chawla@anzup.org.au T: +61 2 8036 5271
- Coordinating PI: Craig Gedye E: craig.gedye@newcastle.edu.au
- ANZUP ClinTrial Refer app available for download from [iTunes](#) and [Google Play](#)

