

PCR MIB Trial News

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From Andrew Weickhardt, PCR-MIB Study Chair:

“PCR-MIB has recruited a total of 24 out of planned 30 patients. The data that was presented from analysis of safety and outcomes from the first 10 patients at ASCO GU 2020 was encouraging. It highlighted a limited but predictable number of side effects of the combination therapy.

With only 6 patients required to complete recruitment - we are almost there!”

Current Recruitment

Everyone should be feeling great about the recruitment to PCR-MIB. At present, 24 patients have been registered to the study. We have surpassed the 80% mark and only 6 more patients until we complete enrolment.

The data that was presented from analysis of safety and outcomes from the first 10 patients at ASCO GU 2020 was encouraging. It highlighted a limited but predictable number of side effects of the combination therapy. Complete responses to therapy were seen in 9 out of 10 patients.

In the last half of 2020, 4 patients were registered. A fantastic achievement given that recruitment for the study has been low. Congratulations to Royal North Shore for boosting the recruitment in the last quarter of 2020. Sir Charles Gairdner and Austin have also been recruiting well.

The opening of a large randomised trial that compares chemotherapy and radiation with and without pembrolizumab is founded in part on our small study – we should be proud and use our momentum to find those 6 remaining patients. Thanks again to all our sites for helping us reach the 80% target.

***A/Prof Andrew Weickhardt
PCR-MIB Study Chair***



***PCR-MIB is a collaboration
between ANZUP and BaCT***



Interim Analysis:

The last interim analysis was done in November 2019 when 10 patients had completed 31 weeks of follow up after treatment. The data from this interim analysis was reviewed, and the conclusion was the study would continue unchanged, and recruitment would continue.

SAE Reporting:

Please remember to report SAEs on the SAE form to BaCT, ANZUP and Merck Global Safety within 24 hours of notification. Ensure one term is listed per SAE form. Multiple SAE forms can be used in cases where there are more than one term for the SAE.

PCR-MIB Database:

PI Oversight of Data

Site Principal Investigators are required to confirm the accuracy of completed eCRFs by routinely logging into Viedoc (the PCR-MIB electronic data capture [EDC] system) and signing completed forms on a quarterly basis. Reminder emails are sent on a quarterly basis with instructions on completing the data sign-off.

Source Data Request

Congratulations to all sites for submitting source data for the study in a timely manner. It has ensured that data management remains up to date and any issues can be addressed promptly.



PCR-MIB key contacts

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