

PCR MIB Trial News

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Welcome to the PCR MIB newsletter

Since opening the first sites in August 2016, 4 patients have been recruited to PCR MIB. To help boost recruitment over the next 12 months, please consider reminding your colleagues at the MDT meetings about the study. We can provide slides and supporting information to assist. If you have a patient with non-metastatic, muscle invasive bladder cancer who wishes to attempt bladder preservation therapy or is ineligible for cystectomy, why not refer them to the PCR MIB Trial.

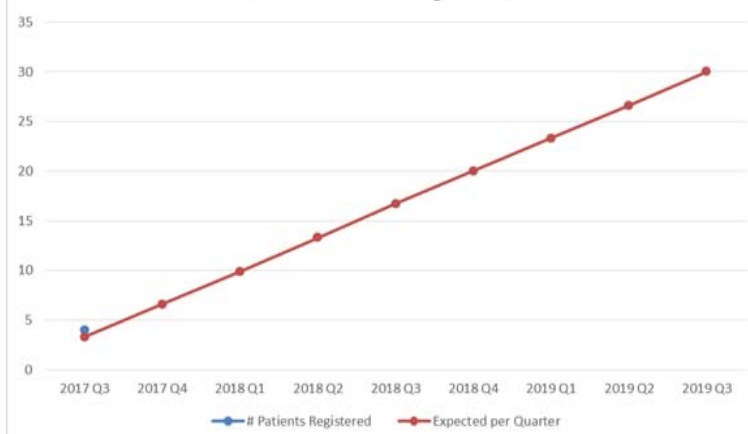
What you need to know

- Chemoradiotherapy leads to outcomes similar to cystectomy. However, chemoradiotherapy does not cure everyone and many people go on to require cystectomy, or have local relapse, or develop distant metastatic disease.
- Approximately 30% of patients do not achieve a complete response to therapy, with a relapse rate of 10% with local-regional disease, and 9-20% distant metastatic disease over 2 years. Improvements in these outcomes are desired.
- The use of drugs such as pembrolizumab is transforming cancer medicine, and checkpoint inhibitors are resulting in unprecedented disease response rates and longer- term control.
- Pembrolizumab is a novel antibody to PD1, which has shown activity as an immunomodulating agent in a range of cancers. In preliminary trials of pembrolizumab in metastatic bladder cancer, 26% of patients experienced a radiological response, and at least 60% of patients had tumour shrinkage.

PCR MIB is a collaboration between ANZUP and BaCT



PCR-MIB: Patient Registrations

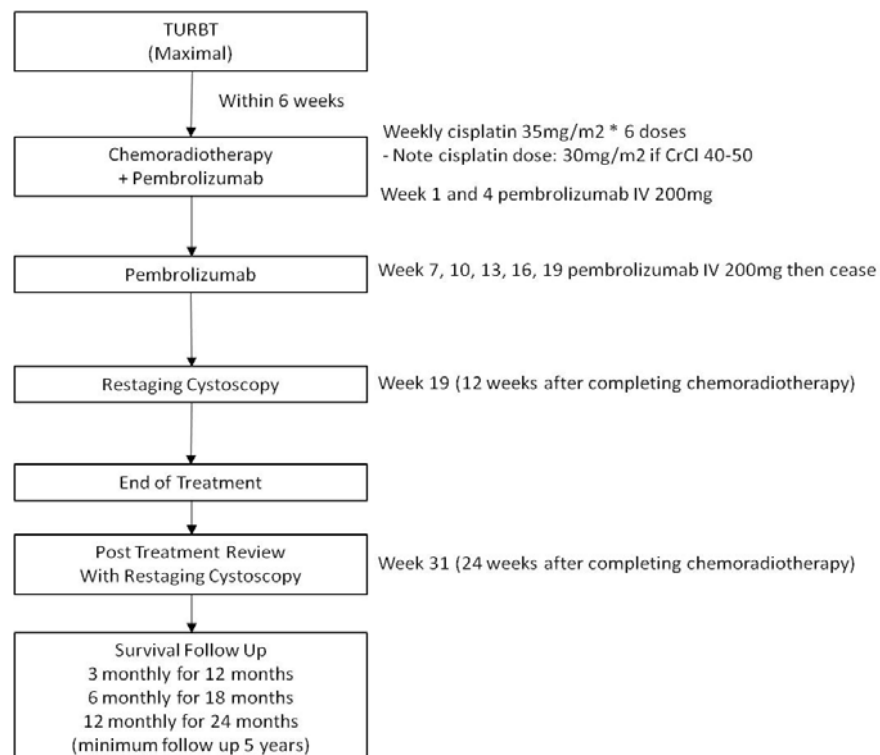


Current recruitment

Austin Health, Prince of Wales Hospital, Chris O'Brien Lifehouse and Sir Charles Gairdner are all open and actively supporting the trial. Royal North Shore Hospital is in the process of submitting to ethics and also hopes to be open shortly.

Site	Patients
Austin Health	3
Chris O'Brien Lifehouse	1
Total	4

Study schema



Translational sampling tips

These **best practice tips** will help with translational sample collections and avoid data queries and protocol deviations:

Tip #1: Both FFPE blocks and slides are acceptable for the trial, however FFPE blocks are preferred

Tip #2: Request samples from pathology centres once consent has been provided

Tip #3: Tissue samples should be sent to the central laboratory only when requested

Tip #4: Always include a de-identified copy of the pathology report when shipping specimens

Tip #5: Blood and urine samples must be collected within 72 hours of commencing chemoradiotherapy

Radiating credentialing tips

These **best practice tips** will help you with radiation credentialing and avoid protocol violations:

1. Real-time review of radiation therapy plans to occur for the first 2 cases
2. RT treatment plans submitted for review should be calculated and approved by the prescribing radiation oncologist prior to submission
3. Reviews **MUST** be undertaken within the first two weeks (10 fractions) following treatment commencement
4. All submitted data must be de-identified
5. If a major protocol violation is identified, additional real-time review cases must be submitted until two consecutive cases meet the trial requirements



ANNUAL SCIENTIFIC MEETING
8-10 JULY 2018
HYATT REGENCY SYDNEY

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PCR MIB key contacts

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- ANZUP ClinTrial Refer app available for download from [iTunes](#) and [Google Play](#)

