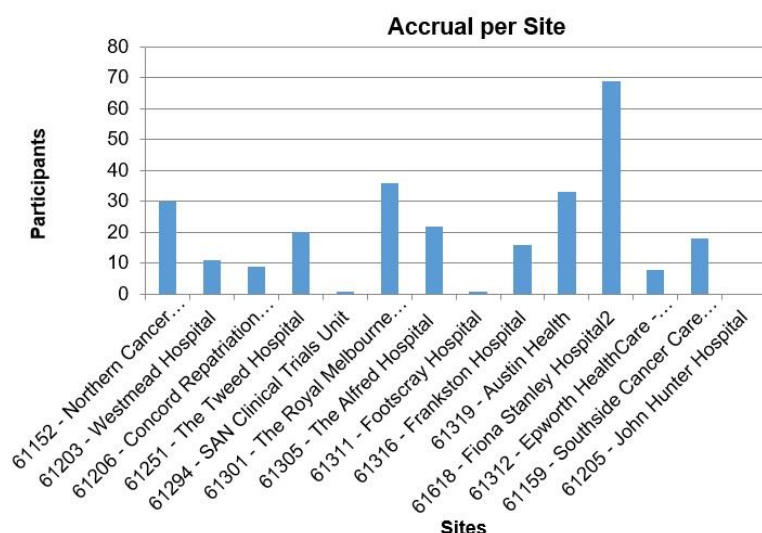


# BCG+MM Trial News

[www.anzup.org.au](http://www.anzup.org.au)

## Welcome to the first edition of the BCG+Mitomycin trial newsletter for 2020

Thank you to everyone for your incredible contribution and efforts to recruit patients to this randomised phase 3 trial for high-risk, non-muscle-invasive bladder cancer. BCG+Mitomycin has now recruited 274 patients, including 24 patients since the last update in November 2019.



### Study accrual

Target recruitment: 500  
 Number of patients randomised: 274  
 Sites open to recruitment: 14



### Study Chair

**Professor Dickon Hayne**

We are grateful to Cancer Australia for their financial support for stage one to conduct the study. We also acknowledge NHMRC funding support for stage two.



**Australian Government**  
**Cancer Australia**

BCG+MM is being led by  
 ANZUP Cancer Trials  
 Group in collaboration with  
 The NHMRC CTC.



We also thank MSD for access to OncoTICE® for our trial patients.



We would like to thank Omegapharm for the supply of Mitomycin.

**OMEGAPHARM**

## IMPORTANT TO REMEMBER

BCG+MM study helps preserve BCG stocks at your site for patients on and off the study. Arm B (the BCG + Mitomycin combination arm) require fewer BCG instillations, assisting with preservation of BCG stocks. MSD Australia have agreed to support the trial by providing BCG OncoTICE® stock to boost supply across BCG+Mitomycin trial sites.

## BCG OncoTICE® shortage update

As you know, there is currently a worldwide shortage of BCG OncoTICE®. During this shortage, MSD Australia have agreed to support the trial by providing BCG OncoTICE® stock to boost supply across BCG+Mitomycin trial sites. This support has allowed the study to remain open and actively recruiting. Please be aware that allocation numbers from MSD are valid only for that month, i.e. when you receive the July 2020 allocation from CTC, you need to place the order by end of the month specifying the allocation number and “ANZUP” in the order form, otherwise the allocation will be considered void.

If your site is currently not impacted by the shortage and you don't require trial allocated stock, randomisations can proceed as normal. However, if your site is solely reliant on the trial allocation, please email the study mailbox [bcgmmc@ctc.usyd.edu.au](mailto:bcgmmc@ctc.usyd.edu.au) prior to randomising. We want to assure site staff that recruitment for the BCG+Mitomycin study is ongoing, however we will need to stagger randomisations to account for ongoing limited supply of OncoTICE®.



## Alternate strains:

We are also aware of other BCG strains which are being supplied in Australia under the TGA Special Access Scheme as alternative to OncoTICE® at this time of shortage. If your site is looking at using these alternative strains, we strongly urge sites to use these alternatives for non-trial patients, and where possible utilise OncoTICE® for BCG+Mitomycin trial patients.

## Recommendations for the management of urothelial carcinoma of the bladder during this time of BCG shortage:

- Thoroughly counsel patients, especially if sub-optimal management being utilized
- Prioritise which patients receive the available BCG
  - ✓ Patients with primary CIS as highest priority (alternative intravesical therapy being inferior to BCG)
  - ✓ Patients enrolled on the BCG + Mitomycin trial
  - ✓ Patients with high-grade &/or T1 disease over those with multiple or recurrent low-grade Ta disease (Induction rather than maintenance – consider using intravesical chemotherapy for maintenance, although data limited)
- Maximize the number of patients who can be treated, i.e. use half or third dose treatment if practically feasible (note: vials may only be utilised on same day)
- Utilise intravesical chemotherapy, early cystectomy or close observation with periodic cystoscopy and resection as alternatives (as detailed below) as required

## COVID-19

It has been a stressful period for researchers and healthcare professionals. We want to thank everyone for their continued commitment to the BCG+Mitomycin study and for quickly implementing the COVID-19 specific guidance provided to you over the past couple of months. Please continue to keep us notified of changes at your site including lifting of recruitment suspensions.

Please continue to send the COVID-19 deviation logs to the study mailbox and ensure that deviations resulting for COVID-19 are clearly documented according to site documentation processes.

COVID-19 related deviations should be documented properly in InForm and the reason clearly stated to avoid queries. For example, if a cystoscopy has not been performed due to COVID-19, please complete the eCRF in the following manner:

- Record the reason for missed/delayed cystoscopy on the Patient Status Form “Was a cystoscopy performed prior to treatment being given at this visit” enter a comment using the comment bubble: COVID-19 outbreak

For further guidance, please refer to the updated BCG+Mitomycin COVID-19 Trial Conduct Guidance Document.

***Thank you for your ongoing support for the BCG+Mitomycin trial. As always, please don't hesitate to contact the study mailbox [bcgmmc@ctc.usyd.edu.au](mailto:bcgmmc@ctc.usyd.edu.au) if you have any questions.***

## BCG+MM key contacts

- ANZUP - lead collaborative group: [anzup@anzup.org.au](mailto:anzup@anzup.org.au)
- Clinical trial operations: [bcgmmc@ctc.usyd.edu.au](mailto:bcgmmc@ctc.usyd.edu.au)
- Coordinating PI - Dickon Hayne: [dickon.hayne@uwa.edu.au](mailto:dickon.hayne@uwa.edu.au)
- Trial information: <https://www.anzup.org.au/content.aspx?page=trials-bcgmmc>