ANZUP Cancer Trials Group Limited

BCG+MM Trial News

www.anzup.org.au

Welcome to the September 2021 edition of the BCG+MM trial newsletter

Thank you to everyone for your continued support and efforts to recruit patients to this randomised phase 3 trial for high-risk, non–muscle-invasive bladder cancer. There have been 59 participants recruited in 2021 so far, already surpassing the total number of participants recruited in 2020! Well done to all sites for continuing to screen and recruit through adversity and helping to bring our total to **371** participants.

Study accrual

Target recruitment: 500
Number of patients randomised: 371
Sites open to recruitment: 15

Study accrual by site

Site Name	State	Investigator	Activation Date	Recruited
Fiona Stanley Hospital	WA	Dickon Hayne	2 Dec 2013	102
Northern Cancer Institute, St Leonards	NSW	Laurence Krieger	11 Feb 2014	45
Royal Melbourne Hospital	VIC	Paul Anderson	11 Feb 2014	41
Austin Health	VIC	Joseph Ischia	18 Mar 2015	40
The Tweed Hospital	NSW	Ratnesh Srivastav	18 Nov 2015	28
The Alfred Hospital	VIC	Jeremy Grummet	12 May 2014	23
Frankston Hospital	VIC	Emma Beardsley	11 Mar 2015	21
Southside Cancer Care Centre	NSW	Patricia Bastick	28 Jul 2017	21
Westmead Hospital	NSW	Manish Patel	17 Mar 2017	12
Concord Repatriation General Hospital	NSW	Andrew Mitterdorfer	28 Jul 2014	9
Epworth HealthCare (Richmond)	VIC	Shomik Sengupta	23 Jan 2016	8
John Hunter Hospital	NSW	Alison Blatt	29 Nov 2019	6
Nottingham University Hospital	UK	William Green	29 Apr 2021	5
Nepean Hospital	NSW	Matthew Winter	27 Oct 2020	4
Redcliffe Hospital	QLD	Matthew Roberts	29 Mar 2021	4
Footscray Hospital*	VIC	Conrad Bishop	21 Aug 2014	1
SAN Clinical Trials Unit*	NSW	Gavin Marx	25 Feb 2015	1
			Total	371

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.

NHMRC Clinical Trials Centre

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

MSD

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

OMEGAPHARM

Participant eligibility

In general, **all** patients suitable for BCG treatment should be suitable for study participation. As such, we encourage you to consider enrolling all new patients about to undergo BCG treatment to the study.
Please record all patients considered for recruitment on your Patient Screening Log and include specific reasons for non-participation. A reminder will be sent each month to send an updated Screening Log to the BCG+MM team. For any questions regarding participant eligibility, please contact the BCG+MM study team.

OncoTICE® study allocation increased

We would like to express our gratitude to MSD Australia for their continued support of the BCG+MM study. MSD Australia have kindly agreed to **significantly increase** the monthly OncoTICE® allocation to the study, greatly assisting the study through the global BCG shortage.

With the increased supply of OncoTICE® available to the BCG+MM study, we highly recommend you consider enrolling your new patients about to undergo BCG treatment to the study if eligible. We encourage you to screen all eligible patients for enrolment to the study and to utilise your referral pathways for referral of appropriate patients.

Although we anticipate more freedom to recruit new patients with the increased supply, please email **BCGMMC.study@sydney.edu.au** prior to randomising, if your site is solely reliant on study allocated OncoTICE®. We would like to ensure enough stock can be allocated to your site for existing and potential new patients.

If your site is not impacted by the shortage and does not require study allocated stock, randomisations can proceed as normal.

Safety update

There have been two instances of BCG-related infective arteritis (mycotic aneurysm) events reported in the study to date. Investigators are reminded this is an expected possible adverse effect of BCG treatment, albeit very rare.

Please notify the BCG+MM team of all study treatment-related serious adverse events.
Further information is available in the OncoTICE® Product Information and Consumer Medicine Information sheets.

An Independent Data Safety Monitoring Committee was held in July 2021. There were no significant safety concerns identified and the recommendation was to continue the trial as per protocol.

Reminders

Pre-Progression Follow-Up Visits

Friendly reminder to all sites that the expected dates for Pre-Progression Follow-Up visits are calculated from the participant's randomisation date, **not** their most recent study visit. The expected date of Pre-Progression Follow-Up Visit 1 is 15 Months from the date of randomisation.

Serious adverse event reporting

Please ensure Serious Adverse Events (SAEs) are reported to the BCG+MM team **within 24 hours** of you becoming aware of the event. Please report all **treatment related** SAEs, even if the event occurs 30 days after the final study dose specified in the current protocol. If in doubt, please contact the BCG+MM study team for assistance and clarification.

SAE reporting is done through our electronic CRF system, InForm. Please make every effort to answer all fields prior to submitting the report on InForm. If InForm is unavailable, a paper based SAE form should be completed and signed by a delegated investigator then sent to the BCG+MM study team.

COVID-19

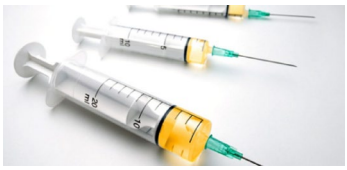
As the effect of COVID-19 differs greatly between regions and difficult to predict, please notify the BCG+MM study team of any changes at your site directly related to COVID-19. Please continue to send the COVID-19 deviation logs to the study mailbox and ensure that deviations resulting for COVID-19 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.

Guidance for COVID-19 vaccinations:

All patients with cancer, including clinical trial participants, should be encouraged in the strongest terms to receive COVID-19 vaccination of any type at the earliest opportunity.



Sites should follow their standard local policies regarding eligibility for vaccination, and its timing, for participants undergoing the same (or similar) treatments as part of routine clinical practice. Trial participation does not affect a trial participant's eligibility or timing for vaccination. Vaccination should not affect a participant's participation in a clinical trial. There are no general restrictions on trial participants who are vaccinated against COVID-19. If safe and feasible we suggest that vaccination take place several days before or after study treatments to help distinguish and attribute symptoms should an immunisation reaction occur.

Vaccination should not affect the trial's schedule of assessments, eligibility, screening or randomisation. Vaccination does not require withdrawal from a trial. If new pertinent information arises during the course of the vaccination programs globally, then updates to this guidance will be provided.

Thank you for your ongoing support for the BCG+MM trial. As always, please don't hesitate to contact the study mailbox BCGMMC.study@sydney.edu.au if you have any questions.

BCG+MM key contacts

- **ANZUP - lead collaborative group:** anzup@anzup.org.au
- **Clinical trial operations:** BCGMMC.study@sydney.edu.au
- **Coordinating PI - Dickon Hayne:** dickon.hayne@uwa.edu.au
- **Trial information:** https://anzup.org.au/clinical-trial/bcgmm-trial/