ANZUP 1301

ANZUP Cancer Trials Group Limited

BCG+MM Trial News

www.anzup.org.au

Welcome to the third edition of the BCG+Mitomycin 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.

Despite the challenges of COVID-19 and the ongoing global BCG shortage, there have been 77 patients recruited since the last update, bringing our total to **351** patients.

Study accrual

Target recruitment: 500

Number of patients randomised: 351

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	98
Northern Cancer Institute, St Leonards	NSW	Laurence Krieger	11 Feb 2014	43
Royal Melbourne Hospital	VIC	Paul Anderson	11 Feb 2014	41
Austin Health	VIC	Joseph Ischia	18 Mar 2015	36
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	20
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	4
Nepean Hospital	NSW	Matthew Winter	27 Oct 2020	4
Redcliffe Hospital	QLD	Matthew Roberts	29 Mar 2021	2
Footscray Hospital*	VIC	Conrad Bishop	21 Aug 2014	1
SAN Clinical Trials Unit*	NSW	Gavin Marx	25 Feb 2015	1
Nottingham University Hospital	UK	William Green	29 Apr 2021	0
			Total	351

Site pending closure

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.

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Updated contact details

Please note the NHMRC Clinical Trials Centre email addresses have changed to the unified University format (@sydney.edu.au). Emails sent to the previous study email address are being forwarded to our new email address for the time being. To ensure we receive your emails, please update the study email address in your contact list to: **BCGMMC.study@sydney.edu.au**

BCG OncoTICE® study allocation increased

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

With the increased supply of OncoTICE® available to the BCG+Mitomycin 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 there to be 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.

Please contact **BCGMMC.study@sydney.edu.au** if you have any eligibility queries.

Site updates

We would like to welcome **Redcliffe Hospital (QLD)** and **Nottingham University Hospital (UK)** to the study! Redcliffe Hospital became our first QLD site in March 2021 and recruited their first patient within one month of activation. Congratulations to the Redcliffe team!

Nottingham University Hospital is the first international site to join the study and we are delighted to have the team on board. The team have been on the lookout for potential participants and expects to recruit their first patient soon.

Thank you to everyone who contributed to the activation of both sites!

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+Mitomycin team within 24 hours of you becoming aware of the event. SAE reporting is done through our electronic CRF system, InForm.

COVID-19

As the effect of COVID-19 differs greatly between regions and difficult to predict, please notify the BCG+Mitomycin Study team of any changes at your site directly related to COVID-19.

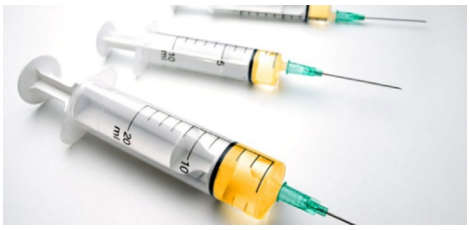
Please continue to send the COVID-19 deviation logs to the study mailbox and ensure that deviations resulting from COVID-19 are clearly documented according to site documentation processes.

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:

Trial participants should be vaccinated against COVID-19 according to the locally applicable standard of care and guidelines.



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+Mitomycin 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://www.anzup.org.au/content.aspx?page=trials-bcgmmc