ANZUP Cancer Trials Group Limited

BCG+MM Trial News

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Welcome to the 6th edition of the BCG+MM trial newsletter

A total of **49 new participants** has been recruited since January 2022! We're now just 53 participants away from reaching our target of 500. Wrapping up recruitment in 2022 is within reach, but we'll need your assistance (and some luck) to do it!

In general, the study will be suitable for most patients being considered for BCG. Please consider enrolling all new patients about to undergo BCG treatment to the study.

For any eligibility queries, please contact **BCGMMC.study@sydney.edu.au.**

Many thanks to all for continuing to support the study!

Study accrual

Target recruitment: 500
Number of patients randomised: 447 (as at 13 July 2022)
Sites open to recruitment: 17

Study accrual by site

Site Name	State	Investigator	Activation Date	Recruited
Fiona Stanley Hospital	WA	Dickon Hayne	2 Dec 2013	118
Northern Cancer Institute, St Leonards	NSW	Laurence Krieger	11 Feb 2014	59
Austin Health	VIC	Joseph Ischia	18 Mar 2015	50
Royal Melbourne Hospital	VIC	Paul Anderson	11 Feb 2014	42
The Tweed Hospital	NSW	Ratnesh Srivastav	18 Nov 2015	34
The Alfred Hospital	VIC	Jeremy Grummet	12 May 2014	23
Nottingham University Hospital	UK	William Green	29 Apr 2021	22
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
John Hunter Hospital	NSW	Alison Blatt	29 Nov 2019	12
Concord Repatriation General Hospital	NSW	Andrew Mitterdorfer	28 Jul 2014	10
Redcliffe Hospital	QLD	Matthew Roberts	29 Mar 2021	9
Epworth HealthCare (Richmond)	VIC	Shomik Sengupta	23 Jan 2016	8
Nepean Hospital	NSW	Matthew Winter	27 Oct 2020	4
Footscray Hospital	VIC	Conrad Bishop	21 Aug 2014	1
SAN Clinical Trials Unit	NSW	Gavin Marx	25 Feb 2015	1
			Total	447

Study Chair

Professor Dickon Hayne

OncoTICE® study allocation

We would like to extend our thanks to MSD Australia for their ongoing support of the BCG+Mitomycin Study. MSD Australia have greatly assisted throughout the global BCG shortage by providing participating study sites access to OncoTICE® each month.

We encourage you to consider enrolling all patients who are about to undergo BCG treatment to the study.

Safety

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 rare.

Further information is available in the OncoTICE Product Information and Consumer Medicine Information sheets.

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.

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.
SAE reporting is completed through our electronic CRF (InForm).

Please answer all fields prior to submitting the report on InForm if possible. Once all available information has been entered, click the “Submit” button to ensure the CTC Team are notified of the SAE.

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.

Reminders & Updates

Patient Screening Logs

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+Mitomycin team.

Reminders & Updates, cont…….

Delegation of Authority Logs

Ensure an updated delegation log is sent to BCGMMC.study@sydney.edu.au each time there is a change in staff at your site. This includes start/end dates for delegated coordinators, investigators and pharmacists.

Quality of Life Questionnaires

Please check QOL Questionnaires for completeness/correctness prior to sending to the study team. In particular:

- Check the participant details written on the QOL matches the details entered in InForm at enrolment (i.e., pt ID, initials, DOB)
- Check all pages of the QOL have been scanned and are included in your attachment
- Enter the QOL details on InForm in the appropriate study visit tab

Data Query Management

Please make every effort to address open queries in the database within two weeks of the query being opened.

Pre-Progression Follow-Up Visits

The expected dates for Pre-Progression Follow-Up visits are calculated from the participant's randomisation date, not the most recently completed study visit.
The expected date of Pre-Progression Follow-Up Visit 1 is 15 Months from the date of randomisation.

A visit calculator tool has been provided to all sites, which can assist in scheduling future study visits.
A blank template is available upon request.

Follow up visit forms not appearing in InForm (Pre-progression and Post-Progression)

Our Data team have been unable to resolve a database issue that is preventing Pre- and Post-progression follow-up visit forms triggering automatically in InForm.

The BCG team have been manually activating follow up forms in bulk on a regular basis as a workaround. Completion of the End of Treatment (EOT) form is a prerequisite for the activation of the follow-up forms.
If you require the follow-up visit tab and the EOT form has been completed, please notify the study team and include the pt ID number in your email.

Reminders & Updates, cont…..

Assessment/Treatment Delays resulting from COVID-19

Please continue to send the COVID-19 deviation logs to the study mailbox and ensure that deviations directly 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

Thank you for your ongoing support for the BCG+MM trial. If you have any questions, please feel free to contact the study team at BCGMMC.study@sydney.edu.au or ANZUP at trials@anzup.org.au.

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 thank MSD for access to OncoTICE® for our trial patients

MSD

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

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BCG+MM key contacts

- **ANZUP - lead collaborative group:** trials@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/