ANZUP Cancer Trials Group Limited

BCG+MM Trial News

www.anzup.org.au

We are just FIVE participants away from reaching our recruitment target of 500!

Please continue screening patients and consider enrolling all new patients about to undergo BCG treatment to the study.

In general, most patients who are suitable for BCG treatment should be suitable for participation in the study.

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

Many thanks to all for your continued support!

Study accrual

Target recruitment: 500
Number of patients randomised: 495 (as at 31 March 2023)
Sites open to recruitment: 18

Study accrual by site

Site Name	State	Investigator	Activation Date	Recruited
Fiona Stanley Hospital	WA	Dickon Hayne	2 Dec 2013	125
GenesisCare North Shore	NSW	Laurence Krieger	11 Feb 2014	68
Austin Health	VIC	Joseph Ischia	18 Mar 2015	58
Royal Melbourne Hospital	VIC	Paul Anderson	11 Feb 2014	43
The Tweed Hospital	NSW	Ratnesh Srivastav	18 Nov 2015	38
Nottingham University Hospital	UK	William Green	29 Apr 2021	33
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
John Hunter Hospital	NSW	Alison Blatt	29 Nov 2019	17
Westmead Hospital	NSW	Manish Patel	17 Mar 2017	12
Concord Repatriation General Hospital	NSW	Andrew Mitterdorfer	28 Jul 2014	12
Redcliffe Hospital	QLD	Matthew Roberts	29 Mar 2021	10
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
Flinders Medical Centre	SA	Alexander Jay	09 Dec 2022	0
			Total	495

Study Chair

Professor Dickon Hayne

Data Entry Prioritisation

As we approach recruitment closure, our focus will shift towards the next exciting stage of the study – data analysis and publications.

We would like to commence data analyses as soon as possible, and we will require your assistance to achieve this. Please ensure data has been entered for all completed study visits to date.

A regular reminder email will be sent to site coordinators to flag overdue data in InForm.

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

Data entry and data collection guidance documents have been provided to all sites previously and are available upon request:

1. BCGMM eCRF completion generic guidelines, v3.0 14Feb2018
2. BCGMM eCRF Training slides, v4.0 14Feb2020
3. BCGMM QOL instructions, v1.0 12Nov2013

For all data entry questions, please contact **BCGMMC.study@sydney.edu.au**.

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 very 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.

Serious Adverse Event Reporting, cont…..

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 you do not receive an email from the BCG+MM team acknowledging receipt of your SAE report, please email BCGMMC.study@sydney.edu.au to confirm the SAE was received. Include the participant ID number in your email.

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 and Updates

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

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 participant ID number in your email.

Upcoming Public Holiday Closure

ANZUP and the NHMRC Clinical Trials Centre (CTC) will be closed for the Easter Public Holidays from 5pm AEST Thursday 6 April 2023 and will re-open 9am AEST Tuesday 11 April 2023.

The randomisation and eCRF systems will be available during this period. However, CTC staff will not be available to respond to emails during the closure. Thank you in advance for your patience during this period.

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.

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

We are grateful to Cancer Australia for their financial support for Stage 1 and the NHMRC funding support for Stage II.

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

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

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/