ANZUP 1301

ANZUP Cancer Trials Group Limited

BCG+MM Trial News

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Welcome to the 5th edition of the BCG+MM trial newsletter

Participant number **400** was recruited by the Nottingham University Hospital team - a great start for 2022. We would like to extend our thanks to the Nottingham team for becoming one of the most active recruitment sites in a short space of time. Despite many challenges, **87** participants were recruited in 2021. That's the highest recruitment total in any year of the study, surpassing our previous highest of 66 in 2019.

Many thanks to all for continuing to support the study!

Study accrual

Target recruitment: 500

Number of patients randomised: 413 (as at 21 March 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	112
Northern Cancer Institute, St Leonards	NSW	Laurence Krieger	11 Feb 2014	50
Austin Health	VIC	Joseph Ischia	18 Mar 2015	47
Royal Melbourne Hospital	VIC	Paul Anderson	11 Feb 2014	42
The Tweed Hospital	NSW	Ratnesh Srivastav	18 Nov 2015	32
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
Nottingham University Hospital	UK	William Green	29 Apr 2021	15
Westmead Hospital	NSW	Manish Patel	17 Mar 2017	12
Concord Repatriation General Hospital	NSW	Andrew Mitterdorfer	28 Jul 2014	9
Redcliffe Hospital	QLD	Matthew Roberts	29 Mar 2021	8
Epworth HealthCare (Richmond)	VIC	Shomik Sengupta	23 Jan 2016	8
John Hunter Hospital	NSW	Alison Blatt	29 Nov 2019	7
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	413

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.

ΩMEGAPHARM

Participant eligibility

In general, most 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+Mitomycin team.

For any questions regarding participant eligibility, please contact the BCG+MM study team.

OncoTICE® study allocation

We would like to extend our thanks to MSD Australia for their continued 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. However, we would still like to ensure enough stock can be allocated to your site for current and potential new study participants. If your site is solely reliant on study allocated OncoTICE® for trial participants, please email **BCGMMC.study@sydney.edu.au** prior to enrolment.

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

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.

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.

Reminder: 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

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
Friendly reminder 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.

Assessment/Treatment Delays resulting from 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 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

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.

#ANZUP22 – Registrations & Abstracts now open!

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/