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## 1. BACKGROUND AND RATIONALE

- Adjuvant intravesical BCG decreases recurrence and progression in people with high-risk NMIBC, however recurrence occurs in 30% despite optimal therapy.
- Meta-analyses evaluating the addition of intravesical MM to BCG showed lower rates of recurrence and cancer-specific mortality in people with NMIBC who received combination regimens.
- The BCGMM trial will be the largest randomized study to date evaluating this approach in people with high-risk NMIBC.
- If this approach is efficacious, the number of patients requiring radical cystectomy, irradiation, and systemic chemotherapy will be reduced.

## 2. AIM

To determine the effects of adding intravesical MM to standard intravesical therapy with BCG after resection of high-risk NMIBC.

## 3. STUDY DESIGN

**Design:** Open label phase 3 trial randomizing participants in a 1:1 ratio to receive intravesical BCG in the standard arm or intravesical BCG and MM in the experimental arm.

**Stratification:** Stage, site of disease, and presence of carcinoma in-situ.

**Target population:** Participants with resected high-risk NMIBC suitable for BCG (high grade Ta or any grade T1).

**Sample size:** 130 participants in Stage 1 gives 95% power to distinguish completion rates of ≥70% (satisfactory) versus ≤50% (unsatisfactory) in each arm at a significance level of 5%.

A further 370 participants in Stage 2 to make up a sample size of 500 gives 85% power to detect a 10% improvement in 2-year DFS at a significance level of 5%.

## 4. STUDY OBJECTIVES

**Stage 1 primary objective:** Rates of treatment completion.

**Stage 2 primary objective:** Disease free survival defined by evidence of transitional cell carcinoma (TCC) or death.

**Secondary objectives:**

- Activity (no recurrence on cystoscopy at 3 months)
- Time to recurrence of TCC
- Time to progression
- Safety
- Health-related quality of life
- Overall survival
- Feasibility

**Tertiary objectives:**

Exploratory biomarkers studies for potential prognostic or predictive biomarkers of treatment.

## 5. STUDY SCHEMA

	Induction										Maintenance															
Arm A	B	B	B	B	B	B					B	B	B	B	B	B	B	B	B	B	B	B				
Weeks	1	2	3	4	5	6	7	8	9	11	13	17	21	25	29	33	37	41	45	49	52					
Cystoscopy and biopsy before 3 months											Cystoscopy and biopsy at 6 and 9 months															
Arm B	B	B	M	B	B	M	B	B	M		M	M	B	M	M	B	M	M	B							
Weeks	1	2	3	4	5	6	7	8	9	11	13	17	21	25	29	33	37	41	45	49	52					

Arm A = Standard  
Arm B = Experimental

B = BCG  
M = MM

## 6. STUDY PROGRESS

As of 17 December 2019, 228 participants have been recruited from 13 sites.

Successful treatment completion has been achieved in 76% of patients treated in the experimental arm of Stage 1, compared to 60% in those allocated BCG alone.



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