

Trial UPdates

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Below is an update on current ANZUP-led and co-badged Bladder Cancer trials taken from ANZUPs most recent monthly membership update.

PCR MIB Trial: Pembrolizumab with Chemoradiotherapy as treatment for Muscle Invasive Bladder Cancer

Principal investigator: Andrew Weickhardt

Status: Open and recruiting

Date opened: 18 August 2016

Recruitment aim: 30 participants

Patients enrolled: 9 (increase of 3)

This study will enroll patients with maximally resected (via transurethral resection (TURBT) non-metastatic muscle invasive bladder preservation therapy or those who are ineligible for cystectomy.

Patients must have adequate organ function and performance status to receive cisplatin based chemoradiotherapy, and no contraindications to the use of pembrolizumab. The study will enroll 30 patients to be treated with pembrolizumab and radiotherapy.

BCGMM: A randomised phase III trial adding mitomycin C to BCG as adjuvant intravesical therapy for high-risk, non-muscle-invasive bladder cancer

Principal investigator: Dickon Hayne

Status: Open and recruiting

Date opened: December 2013

Recruitment aim: Stage 1: 130 patients / Stage 2: 370 patients

Patients enrolled: 186 (increase of 3)

Instillation of Bacillus of Calmette-Guerin (BCG) into the urinary bladder (intravesical administration) improves rates of disease recurrence and progression after transurethral resection (TUR) of high risk, non-muscle-invasive bladder cancer (NMIBC), but over 30% of people still recur despite optimal therapy with adjuvant intravesical BCG.

Our meta-analysis, including a recent randomised phase 2 trial, suggests that outcomes might be improved further by using an adjuvant intravesical regimen that includes both Mitomycin C (MMC) and BCG.

These promising findings require corroboration in a definitive, large scale, randomised phase 3 trial using standard techniques for intravesical administration.

Co-Badged Trials

[NMIBC-SI Evaluation: Developing a Patient-Reported Symptom Index for Non-muscle Invasive Bladder Cancer](#)

Principal investigator: Manish Patel; Shomik Sengupta

Status: Active and recruiting

Date opened: 01 July 2016

Recruitment aim: 450 participants

Patients enrolled Field test 1: 220 (closed - completed)

Patients enrolled Field test 2: 27 (increase of 14)

The NMIBC-SI study

Field Test 2 opened for recruitment in June 2018.

13 sites across Australia and New Zealand are open to recruitment. Sixteen sites are anticipated: 10 in Australia, 2 in New Zealand, 3 in the US, and 1 in the UK.

The overarching aim of this research is to develop and evaluate a patient-reported Symptom Index (SI) for individuals with NMIBC (the NMIBC-SI) that is acceptable to patients, reliable, valid, and responsive, and fit for purpose in clinical trials and clinical practice.

Please consider these studies in the relevant patient population.