

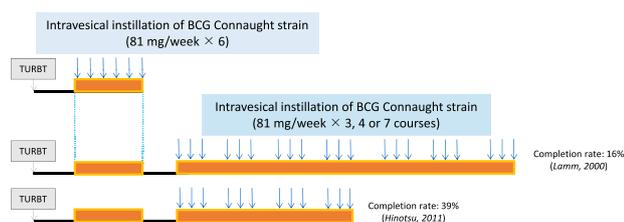
# A randomized control study to evaluate the prevention of recurrence and the safety of BCG (Bacillus Calmette-Guerin) instillation therapies between induction alone and induction + low-dose maintenance in non-muscle invasive bladder cancer

Target disease: Non-muscle-invasive bladder cancer (NMIBC) post transurethral resection of bladder tumor (TURBT)

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## Synopsis

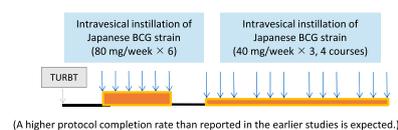
TURBT is standard therapy for NMIBC, which accounts for about 70-80% of bladder cancers. However, 30-70% of the patients show intravesical recurrence of the cancer within 5 years after the surgery, and 10-15% of these advance to muscle-invasive bladder cancer. Once the cancer has advanced to this level, the patient has no choice other than to go in for total cystectomy and urinary diversion, which worsens QOL and prognosis. Therefore, for maintaining better prognosis and QOL of NMIBC patients, it is important to prevent, to the extent possible, any postoperative intravesical recurrence or progression of the cancer in the bladder. Intravesical instillation of BCG has been found to be an effective postoperative adjuvant therapy in preventing post-TURBT recurrence and progression of NMIBC in patients with moderate to high risk of recurrence (*Sylvester RJ (2020)*). Recent studies have demonstrated enhanced effectiveness of giving 1-3 years of maintenance therapy following the induction therapy of intravesical BCG instillation. But this combination therapy has not been widely adopted because of low completion rate due to adverse reactions (*Lamm DL (2000)*, *Hinotsu S (2011)*). On the other hand, there was a report of successful reduction of adverse reactions, while maintaining the same level of prevention of recurrence and progression, by using a reduced dose (*Martinez-Pineiro (2005)*, *Ojea (2007)*). In the proposed study, we intent to verify through a randomized controlled trial (RCT) that post-TURBT standard-dose BCG induction therapy plus low-dose BCG maintenance therapy is superior to standard dose BCG induction therapy alone in preventing recurrence in NMIBC patients with moderate to high recurrence risk, and that it can be administered safely with a high completion rate.



In both the SWOG trial (7 courses of maintenance therapy, Lamm et al., 2000) and the Japanese study (4 courses of maintenance therapy, Hinotsu et al. 2011), maintenance therapy showed significant enhancement of recurrence prevention. However, the completion rate of the maintenance therapy protocol in the trials remained very low, respectively at 16% and 39%, due to high incidence of adverse reactions.

### Objective of the proposed study

To verify the enhancing effect on recurrence prevention and the safety of low-dose BCG maintenance therapy, which reportedly causes low incidence of adverse reactions while having the same level of effectiveness as the standard dose.



**Related keywords :** Bladder cancer, Non-muscle invasive bladder cancer, BCG, Intravesical instillation therapy, Prevention of intravesical recurrence