Prevention and Management of Intravesical BCG-related Lower Urinary Tract Symptoms with Prophylactic Pentosan Polysulphate in Patients with Non-Muscle-Invasive Bladder Cancer: A Randomized Controlled Trial

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STUDY FLOW DIAGRAM

METHODS / INTERVENTIONS

Study Design
• Phase 2, double-blind, randomized, placebo-controlled, parallel-group study
• Multicentre trial involving two partner sites: (Jewish General Hospital, McGill University Health Centre)

Outcomes
Primary outcomes (change from baseline to end of treatment):
• Mean change in number of urgency episodes/24hr (3-day bladder diary)
• Mean change in ICIQ-LUTSqol score
• Mean change in OAB-V8 score

Secondary outcomes (change from baseline to end of treatment):
• Mean change in VAS score
• Mean change in urinary inflammatory markers (TRAIL, IFN, IL-2, IL-10)
• Cystoscopy and urine Cytology at 3 and 6 months

STUDY IMPACT

• Improve patient experience by identifying predictor markers rendering patients at higher risk of developing BCG-related LUTS.
• This will guide patient counselling before treatment to inform about associated risks and benefits of the BCG treatment.
• We will determine the role of prophylactic PPS to prevent these LUTS from occurring, particularly if patients are considered at higher risk, and therefore improve patient experience.
• The improvement measurements are validated in the assessment of lower urinary tract symptoms related to BCG therapy (voiding diary and OAB-V8) and their quality of life (ICIQ-LUTSqol).

REFERENCES

TRANSLATION ACROSS THE RCN

• The proposed study will provide evidence to guide larger scale studies that may change our practice. Evidence-based treatment intervention (Pentosan Polysulphate) will help to improve bladder cancer patients’ quality of life and optimize the effectiveness of BCG treatment.
• This can effectively reduce patient hospital stay and outpatient visits and hence, treatment related cost. Moreover, it will minimize the burden of bladder cancer-treatment-related adverse events in Quebec.
• The proposed study is completely aligned with the MSSS and Direction generale de cancérologie, as it will continue to give highest quality care to NMIBC patients with BCG treatment, as it currently is recommending.
• The study will identify predictive marker to improve informed consent and direct prophylactic measure to avoid complications such as BCG related LUTS.