# Gemcitabine-Docetaxel Intravesical instillation Synchronous CO-administration- A phase I study: G-DISCO (ANZUP 2403)

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## Background and Rationale

Treatment options are limited for patients with BCG-unresponsive or BCG-unsuitable HR-NMIBC. If a patient is unfit for, or declines, radical cystectomy, guidelines recommend intravesical chemotherapy with gemcitabine and docetaxel (GD).

Studies have reported 1-year RFS of 60% and 2-year RFS of 46% in patients treated with intravesical GD. Long-term follow-up (median 49 months) shows a 5-year bladder preservation rate of 75% and CSS of 91% following treatment with intravesical GD.

Traditionally, these agents are administered sequentially, requiring two-hour dwell times for each drug resulting in significant time demands (~5 hours) for patients and healthcare resources.

G-DISCO represents a first-in-human trial of synchronous intravesical administration of gemcitabine and docetaxel.

By combining both agents in a single instillation, this trial explores a novel strategy aimed at reducing procedural burden while maintaining efficacy.

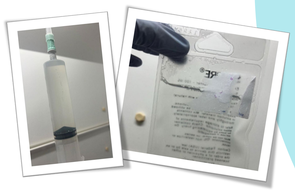

***Figure 1: Gemcitabine-Docetaxel Compatibility Experiments***

## Hypothesis and Aim

The aim of this study is to assess the feasibility, safety and tolerability of synchronous intravesical instillation of gemcitabine and docetaxel in patients with BCG refractory HR-NMIBC who are unsuitable for, or unwilling to undergo, radical cystectomy

Synchronous administration of both agents is likely to have several potential advantages – a significant reduction in time required for both the patient and procedural unit, optimal distribution of the agents in the bladder, less resource intensive for consumables and a more efficient workflow for the procedural unit with a lower carbon footprint

## Objectives

### Co-Primary:

**Safety, feasibility and tolerability of synchronous administration of intravesical gemcitabine and docetaxel**

### Secondary:

**Recurrence rates at 3 months**

**Carbon footprint – synchronous vs concurrent administration**

### Tertiary:

**Biospecimens for translational sub studies**

## Eligibility

- **Fully resected, HR-NMIBC (CIS allowed)**
- **Disease unresponsive to intravesical therapy**
- **Patients not suitable for further intravesical therapy**
- **Patients unsuitable for/declining, radical cystectomy**
- **Age > 18 years**
- **ECOG 0 – 2**

## Intervention

- **Synchronous intravesical co-administration:**

**Gemcitabine 1g + Docetaxel 37.5mg**

- **Both agents constituted together in 50 ml of saline**
- **Total dwell time of 90 minutes**
- **Induction intravesical treatment weekly for 6 weeks**
- **Post treatment GA rigid cystoscopy and bladder biopsies**

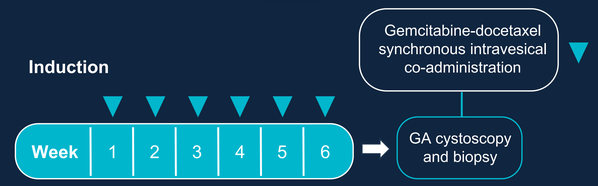


***Figure 2: G-DISCO treatment schedule***

## Study Design

### Target Population:

Patients with fully resected HR-NMIBC, unresponsive to or not suitable for BCG therapy, who are unable or unwilling to undergo radical cystectomy.

### Design:

Investigator initiated

- Single-arm, phase I clinical trial
- Single centre in Australia

### Sample Size:

- 15 patients, based on an estimated 66% completion rate of 6 induction doses (10/15 patients)

## Conclusions

G-DISCO is currently open and recruiting in Australia with a 2 year recruitment strategy expected to close in 2026.

If successful, G-DISCO could establish a new standard for administering intravesical gemcitabine and docetaxel, offering several potential advantages, including:

- Shortened treatment time for patients
- Improved unit time-efficiency and resource savings for healthcare facilities
- Reduced exposure for staff handling these cytotoxic agents
- Smaller carbon footprint compared with synchronous administration

This study is being conducted by the Australian and New Zealand Urogenital and Prostate Trials Group Ltd (ANZUP) in collaboration with South Metropolitan Health Service, Western Australia and the University of Western Australia. ANZUP is supported by the Australian Government through a Cancer Australia infrastructure Grant.

## References


- Holzbeierlein JM, et al. Diagnosis and Treatment of Non-Muscle Invasive Bladder Cancer: AUA/SUO Guideline: 2024 Amendment. Journal of Urology 2024 Apr [7];211(4):533–8.
- Steinberg RL, et al. TJ, Multi-Institution Evaluation of Sequential Gemcitabine and Docetaxel as Rescue Therapy for Nonmuscle Invasive Bladder Cancer. J Urol. 2020 May;203(5):902-909.
- Chevuru PT, et al. Long-term follow-up of sequential intravesical gemcitabine and docetaxel salvage therapy for non-muscle invasive bladder cancer. Urol Oncol. 2023;41(3):148.e1-.e7.


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