

BC Cancer Protocol Summary for Treatment of Muscle Invasive Urothelial Cancer using Gemcitabine and Radiation Therapy

Protocol Code

GUBGRT

Tumour Group

Genitourinary

Contact Physicians

GU Systemic Therapy

ELIGIBILITY:

Patients must have:

- Muscle invasive urothelial cancer (pT2-4, N any and clinical M0), and
- Ineligibility for concurrent CISplatin:
 - Renal insufficiency, creatinine clearance less than 45 mL/min
 - Cardiac disease that results in an intolerance to fluid load
 - Severe neuropathy
 - Marked hearing loss
 - Other significant risk factors that render patient ineligible for concurrent CISplatin however the risk of disease is sufficient to warrant concurrent treatment

Patients should have:

- Good performance status
- Adequate hematologic, renal and hepatic function

EXCLUSIONS:

Patients must not have:

- Prior chemotherapy
- Prior pelvic radiation

TESTS:

- Baseline: CBC & Diff, creatinine, total bilirubin, ALT, alkaline phosphatase
- Before each treatment: CBC & Diff, creatinine
- If clinically indicated: total bilirubin, ALT, alkaline phosphatase

PREMEDICATIONS:

- Antiemetic protocol for low emetogenic chemotherapy protocols (see protocol [SCNAUSEA](#)).

TREATMENT:

Drug	Dose	BC Cancer Administration Guideline
gemcitabine	100 mg/m ² on Days 1, 8, 15 and 22 with concurrent radiation*	IV in 100 mL NS over 30 min

*Concurrent radiation is delivered in 20 fractions over 4 weeks

DOSE MODIFICATIONS:**1. Hematology:**

ANC (x 10 ⁹ /L)		Platelets (x 10 ⁹ /L)	Dose
Greater than or equal to 1.0	and	Greater than or equal to 100	100%
0.5 to less than 1.0	or	75 to less than 100	75%
Less than 0.5	or	Less than 75	Omit

2. Renal Dysfunction:

Creatinine Clearance (mL/min)	Dose
Greater than or equal to 45	100%
Less than 45	Omit if serum creatinine is greater than 3 x ULN

PRECAUTIONS:

- Neutropenia:** Fever or other evidence of infection must be assessed promptly and treated aggressively.
- Renal Toxicity:** Irreversible renal failure associated with hemolytic uremic syndrome may occur (rare) with gemcitabine. Use caution with pre-existing renal dysfunction.
- Pulmonary Toxicity:** Acute shortness of breath may occur. Discontinue treatment if drug-induced pneumonitis is suspected.
- Possible interaction with warfarin** has been reported and may occur at any time. Close monitoring is recommended (monitor INR weekly during gemcitabine therapy and for 1 to 2 months after discontinuing gemcitabine treatment).

Contact GU Systemic Therapy physician at your regional cancer centre or the GU Systemic Therapy Chair with any problems or questions regarding this treatment program.

References:

1. Choudhury A, Swindell R, Logue JP, et al. Phase II study of conformal hypofractionated radiotherapy with concurrent gemcitabine in muscle-invasive bladder cancer. *J Clin Oncol*. 2011 Feb 20;29(6):733-8.
2. Coen JJ, Zhang P, Saylor PJ, Lee CT, et al. Bladder Preservation With Twice-a-Day Radiation Plus Fluorouracil/Cisplatin or Once Daily Radiation Plus Gemcitabine for Muscle-Invasive Bladder Cancer: NRG/RTOG 0712-A Randomized Phase II Trial. *J Clin Oncol*. 2019 Jan 1;37(1):44-51.