BC Cancer Protocol Summary for Treatment of Locally Advanced Squamous Cell Carcinoma of the Head and Neck with Concurrent Weekly DOCEtaxel and Radiation

Protocol Code	*HNLADOCRT*
Tumour Group	*Head & Neck*
Contact Physician	*Dr. Nicole Chau, Medical Oncology* *Dr. Sarah Hamilton, Radiation Oncology*

ELIGIBILITY:

Patients must:

- Have non-metastatic, locally advanced squamous cell carcinoma of the head and neck including unknown primary,
- Be a suitable candidate for radical radiation, and
- Be ineligible for concurrent CISplatin and radiotherapy as per discretion of the treating provider.

Patients should have:

- ECOG performance status 0-2

EXCLUSIONS:

- Patients who are eligible for CISplatin should be treated accordingly as the best evidence supports CISplatin as a radiosensitizer.

SUPPORTIVE CARE:

- Prior to initiation of treatment, patients will be referred for consultation to Dentistry and Nutrition Services
- Placement of a feeding gastrostomy tube prior to treatment is encouraged if there has been significant weight loss (ie., greater than 10% from baseline)
- Standard oral hygiene during treatment (sodium bicarbonate mouth rinse, nystatin/fluconazole for fungal infections, antibiotics for documented infections)

TESTS:

- Baseline: CBC & Diff, creatinine, ALT, alkaline phosphatase, total bilirubin, GGT, LDH
- Baseline (optional, results do not have to be available to proceed with treatment): HBsAg, HBsAb, HBcoreAb
- Before each cycle: CBC & Diff, ALT, alkaline phosphatase, total bilirubin
- If clinically indicated: GGT, LDH, creatinine, HBV viral load

PREMEDICATIONS:

- dexamethasone 8 mg IV 30 minutes prior to DOCEtaxel treatment, then 4 mg PO BID on Days 2 and 3.
- Antiemetics not usually required.

SUPPORTIVE MEDICATIONS:

- If HBsAg or HBcoreAb positive, follow hepatitis B prophylaxis as per current guidelines

TREATMENT:

Drug	Dose	BC Cancer Administration Guideline
DOCEtaxel	15 mg/m^2	IV in 25 to 100 mL NS over 1 hour (use non-DEHP equipment)

Repeat weekly for 7 weeks concurrent with radiation therapy, starting the first day of radiation therapy. Chemotherapy is only to be administered if concurrent with radiation.

DOSE MODIFICATIONS:

1. Hematology:

ANC (x 10^9/L)	Platelets (x 10^9/L)	Dose	Dose after Neutropenic Sepsis on DOCEtaxel
Greater than or equal to 1.5	Greater than or equal to 100	15 mg/m^2	12 mg/m^2
1.0 to 1.4	70 to 99	12 mg/m^2	10 mg/m^2
Less than 1.0	Less than 70	Delay	Delay

2. **Hepatic dysfunction:**

Alkaline phosphatase		ALT		Total bilirubin	Dose
Less than 2.5 x ULN	and	Less than or equal to 1.5 x ULN		-	15 mg/m^2
2.5 to 5 x ULN	and	1.6 to 3 x ULN		-	12 mg/m^2
Greater than 5 x ULN	or	Greater than 3 to 5 x ULN	or	Greater than 2 x ULN	Hold and discuss with contact physician

ULN = upper limit of normal

PRECAUTIONS:

1. **Fluid retention:** Although fluid retention is less likely to occur with weekly DOCEtaxel, dexamethasone premedication must be given to reduce incidence of severity of fluid retention.
2. **Infusion-related reactions:** Reactions are common but it is not necessary to routinely initiate the infusion slowly. If slow initiation of infusion is needed, start infusion at 30 mL/h x 5 minutes, then 60 mL/h x 5 minutes, then 120 mL/h x 5 minutes, then complete infusion at 250 mL/h). See BC Cancer Protocol Summary for Management of Infusion-Related Reactions to Systemic Therapy Agents, SCDRUGRX.
3. **Extravasation:** DOCEtaxel causes pain and tissue necrosis if extravasated. Refer to BC Cancer Extravasation Guidelines.
4. **Neutropenia:** Fever or other evidence of infection must be assessed promptly and treated aggressively.
5. **Hepatic dysfunction:** DOCEtaxel undergoes hepatic metabolism. Hepatic dysfunction (particularly elevated AST or ALT) may lead to increased toxicity and usually requires a dose reduction.

Contact Dr. Nicole Chau or tumour group delegate at 604-877-6000 with any problems or questions regarding this treatment program.

REFERENCES:

1. Patil VM, Noronha V, Menon N, et al. Results of Phase III Randomized Trial for Use of Docetaxel as a Radiosensitizer in Patients With Head and Neck Cancer, Unsuitable for Cisplatin-Based Chemoradiation. J Clin Oncol. 2023 May 1;41(13):2350-2361.

2. Fujii M, Tsukuda M, Satake B, et al. Phase I/II trial of weekly docetaxel and concomitant radiotherapy for squamous cell carcinoma of the head and neck. Int J Clin Oncol 2004;9(2):107–12.
3. Matsumoto F, Karasawa K, Itoh S, et al. Concurrent weekly docetaxel and hyperfractionated radiotherapy for advanced head and neck cancer. Anticancer Res 2006;26(5B):3781–6.
4. Calais G, Bardet E, Sire C, et al. Radiotherapy with concomitant weekly docetaxel for Stages III/IV oropharynx carcinoma. Results of the 98-02 GORTEC Phase II trial. Int J Radiat Oncol Biol Phys 2004;58(1):161–6.
5. Behera M, Owonikoko TK, Kim S, et al. Concurrent therapy with taxane versus non-taxane containing regimens in locally advanced squamous cell carcinomas of the head and neck (SCCHN): a systematic review. Oral Oncol 2014;50(9):888–94.