

BCCA Protocol Summary for Treatment of Head and Neck Cancer Using Methotrexate as Standard Therapy

Protocol Code:

HNAVM

Tumour Group:

Head and Neck

Contact Physician:

Dr. Cheryl Ho

ELIGIBILITY:

check eligibility for clinical trial first

- recurrent head and neck cancer
- any histology except lymphoma or melanoma
- serum creatinine less than 2 x normal
- normal bone marrow function

EXCLUSION:

- third space fluid accumulations (edema, effusion, ascites)

TESTS:

- Baseline: CBC & diff, platelets, creatinine, bilirubin
physical and chest x-ray to rule out third space fluid accumulations
- During treatment: CBC & diff, platelets every 2 weeks
creatinine monthly

PRETREATMENT:

Nausea is infrequent and usually best managed with dimenhydrinate (GRAVOL®) or prochlorperazine (STEMETIL®).

TREATMENT:

- Methotrexate may be given either intravenously **or** orally as follows:

	Drug	Dose	BCCA Administration Guideline
Option 1	Methotrexate	40 mg/m ² ± 10mg/m ² * once weekly	IV Push
Option 2	Methotrexate	20 mg/m ² ± 5 mg/m ² * twice weekly	PO (orally)

*indicates range of starting dose (see BCCA Cancer Drug Manual for more detailed dosage and escalation alternative)

- Each week equals one cycle; patients to receive at least 2 cycles.
- continue treatment until disease progression or toxicity

1. Hematological

ANC (x 10 ⁹ /L)		Platelets (x 10 ⁹ /L)	Dose
greater than 1.5	and	greater than 150	100%
1 – 1.5	or	50 – 150	Physician's discretion: 100% or delay x 1 week and/or dose reduction by 25%
less than 1	or	less than 50	Delay until counts return to normal. Consider dose reduction by 25%

2. Renal Dysfunction

Creatinine clearance (mL/min)	Methotrexate dose
greater than 80	100%
greater than 60	75%
greater than 50	60%
less than 50	Do not give

$$\text{Calculated creatinine clearance} = \frac{N \times (140 - \text{Age}) \times \text{weight (kg)}}{\text{Serum Creatinine in micromol/L}}$$

N for Males = 1.23, Females = 1.04

3. Mucositis*

Grade	Description	Dose
1	painless ulcers, erythema, or mild soreness in absence of lesions	100%
2	painful erythema, edema, or ulcers, but can eat or swallow	Delay x 1 week and reduce dose by 25%
3	painful erythema, edema, or ulcers, cannot eat	Delay until resolves. Consider alternate therapy
4	mucosal necrosis and/or requires parenteral or enteral support	Delay until resolves. Consider alternate therapy

*For patients on oral methotrexate: on day of taking pills at home, patient should test their mouth with orange juice to check for mucositis. If the mouth feels the same as usual with the juice, they can proceed with treatment. Mucositis usually precedes any granulocytopenia seen. If mouth does not feel the same, patient should skip that dose and call the attending oncologist.

Contact Dr. Cheryl Ho or tumour group delegate at (604) 877-6000 or 1-800-663-3333 with any problems or questions regarding this treatment program.

Date activated: N/A

Date revised: 1 Nov 2010 (treatment cycle clarified)

References:

Forastiere A, et al. Phase III randomized comparison of cisplatin plus fluorouracil and carboplatin plus fluorouracil versus methotrexate in advanced squamous-cell carcinoma of the head and neck: A Southwest Oncology Group Study. *J Clin Oncol*1992; 10(8): 1245-51.