

BC Cancer Protocol Summary for DOXOrubicin for Adjuvant Use for Patients with Non-Metastatic Operable Large High Grade Soft Tissue Sarcoma

Protocol Code:	SAAJA
Tumour Group:	Sarcoma
Contact Physician:	<i>Dr Christine Simmons</i>

ELIGIBILITY/TESTS:

- Adult (greater than or equal to 17 years of age) patients with:
 - localized, operable non-metastatic soft tissue sarcoma of the extremity but not rhabdomyosarcoma, Ewing's Family of Tumours (EWFT) in adults.
- or
- high grade aggressive histologies with known poor prognosis
- In certain instances for young patients with aggressive primitive histologies, locally advanced disease or large high grade synovial sarcomas, SAAI may be used - as before
- Patients must have normal cardiac function.
- Radiation therapy will generally follow chemotherapy – but can be given concurrently for selected patients.

TESTS

- Baseline: full clinical evaluation including recent (within 3 months) CT chest, CBC and diff, platelets, [alk phos](#), [ALT](#), [albumin](#), and bilirubin.
- Before each treatment: CBC and diff, platelets
- If clinically indicated: bilirubin, ECG and measure of LVEF

TREATMENT:

Drug	Dose	BC Cancer Administration Guideline
DOXOrubicin (ADRIAMYCIN®)	75 mg/m ²	IV push

Repeat every 3 weeks x 5 cycles only (total dose 375 mg/m²).

DOSE MODIFICATIONS:

1. Hematologic Toxicity: Treatment day counts

ANC* (x 10 ⁹ /L)		Platelets (x 10 ⁹ /L)	Dose
greater than or equal to 1.5	and	greater than or equal to 100	100%
1.0 to less than 1.5	or	70 to less than 100	80%
less than 1.0	or	less than 70	delay one week

* Absolute neutrophil count

2. **Mucositis:** Grade 3 or 4 give 80%
3. **Nausea & Vomiting:** Grade 4 - not helped by antiemetics give 80% of dose or QUIT.
4. **Neutropenic Fever:** with ANC less than 0.5 (x 10⁹/L), give 80% of dose.
5. **Bilirubin** 1.5 - 2 times normal, reconsider advisability of adjuvant chemotherapy.

PRECAUTIONS:

1. **Cardiomyopathy** is a well known toxicity of DOXOrubicin with cumulative dose of the drug over 400 mg/m². Occasionally this may occur with less drug – patients should be screened for any symptoms or signs of arrhythmia or congestive heart failure during therapy and on follow-up.

Call Dr. **Christine Simmons** or tumour group delegate at (604) 877-6000 or 1-800-663-3333 with any problems or questions regarding this treatment program.

Reference:

1. Anonymous (2000). Adjuvant chemotherapy for localised resectable soft tissue sarcoma in adults. Sarcoma Meta-analysis Collaboration (SMAC). Cochrane Database of Systematic Reviews [computer file](2): CD001419.
2. Bramwell V H. Adjuvant chemotherapy for adult soft tissue sarcoma: Is there a standard of care? [letter; comment]. J Clin Oncol 2001;19(5):1235-7.
3. Figueredo A, Bramwell VH, Bell R, Davis AM, Charette ML, et al. Adjuvant chemotherapy following complete resection of soft tissue sarcoma in adults: a clinical practice guideline. Sarcoma 2002;6(1): 5-18.