

BC Cancer Protocol Summary for Therapy for Low Risk Gestational Trophoblastic Cancer using DACTINomycin

Protocol Code

GOTDLRA

Tumour Group

Gynecology

Contact Physician

Dr. Anna Tinker

ELIGIBILITY:

- **Low Risk Gestational Trophoblastic Neoplasm (GTN)** as determined using the modified World Health Organization (WHO) Prognostic Scoring System as adapted by the International Federation of Gynecology and Obstetrics (FIGO).
 - Patients with a risk score of 0 to 4, or **beta hCG** $\leq 10,000$ (if missing items so cannot calculate risk score) are considered low risk
 - The risk score is calculated as follows:

Risk Factor	SCORE			
	0	1	2	4
Age (years)	<40	>40		
Antecedent pregnancy	Mole	Abortion	Term	
Interval (months)*	<4	4-6	7-12	>12
Pre-treatment serum beta hCG (mIU/mL)**	<10 ³	10 ³ -10 ⁴	10 ⁴ -10 ⁵	>10 ⁵
Sites of metastases	Lung	Spleen and kidney	GI tract	Brain and liver
Number of metastases	-	1-4	5-8	>8
Largest tumour size (including uterus) (cm)		3-4	5	
Prior failed chemotherapy	-	-	Single drug	≥2 drugs

* interval (in months) between end of antecedent pregnancy and start of chemotherapy

** use the immediate pre-treatment **beta hCG** - not the peak hCG during pregnancy or prior to uterine evacuation

- **Contact BC Cancer for recommendations if more than one year post normal pregnancy and not currently pregnant**

EXCLUSIONS:

- Moderate and high risk GTN (prognostic score greater than 4). These patients should be treated on the BC Cancer moderate risk protocol GOTDMR (risk score of 5 or 6) and high risk protocol GOTDEMACO (risk score ≥ 7), respectively.

TESTS:

- If the GTN was not confirmed histopathologically (e.g. only products of conception were identified at the time of the dilation and curettage) then a pelvic ultrasound within 5-7 days of treatment initiation is required to rule out a previously undetected viable intra-uterine pregnancy.
- **Baseline:** CBC & differential, [beta hCG tumour marker](#), creatinine, sodium, potassium, bilirubin, ALT, alk phos, LDH, GGT, pelvic ultrasound, chest X-ray, CT brain (if post normal pregnancy, liver mets, or CNS symptoms), CT abdo/pelvis (if post normal pregnancy or if post molar pregnancy with positive chest X-ray)
- **Before each treatment:** CBC & differential, [beta hCG tumour marker](#), bilirubin, ALT, alk phos, LDH, GGT
- If clinically indicated: creatinine, sodium, potassium, chest x-ray

PREMEDICATIONS:

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

TREATMENT:

Drug	Dose	BC Cancer Administration Guideline
DACTINomycin	1.25 mg/m ² (maximum 2 mg)	IV push

Repeat every 14 days. Treat until [beta hCG tumour marker less than 5 mIU/mL](#), and then additional 2 cycles (e.g. if [beta hCG tumour marker](#) is normal at the start of cycle 3, give 4 cycles total)

DOSE MODIFICATIONS:

1. Hematological

ANC (x10 ⁹ /L)		Platelets (x10 ⁹ /L)	Dose
greater than or equal to 1.0	and	greater than or equal to 100	100%
0.7 to less than 1.0	or	75 to less than 100	80%
less than 0.7	or	less than 75	Hold until recovery, then 66%

If further dose reduction is required, use 70% of starting dose

2. Hepatic dysfunction:

Bilirubin (micromol/L)		ALT	Dose
greater than 2 x ULN	or	greater than 5 x ULN	60%

ULN = upper limit of normal

If bilirubin and/or ALT continue to rise despite dose reduction, contact tumour group designate for recommendations

3. Stomatitis: Decrease DACTINomycin to 80% (1 mg/m²)

PRECAUTIONS:

- Neutropenia:** Fever or other evidence of infection must be assessed promptly and treated aggressively. Filgrastim (G-CSF) may be needed to maintain white count.
- Extravasation:** DACTINomycin causes pain and tissue necrosis if extravasated. Refer to BC Cancer Extravasation Guidelines.

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

References:

- Petrilli ES, Twiggs LB, Blessing JA, et al. Single-dose actinomycin-D treatment for nonmetastatic gestational trophoblastic disease. *Cancer* 1987; 60:2173-6.
- Hoskins PJ, Le N, Kumar A, et al. Single or two drug combination therapy as initial treatment for low risk, gestational trophoblastic neoplasia. *A Canadian analysis. Gynecologic Oncology* 2020;157:367-71.