

NORTH CENTRAL CANCER TREATMENT GROUP
N06CA Eligibility Checklist

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N06CA: The Use of Topical Baclofen, amitriptyline HCl, and Ketamine (BAK) in a PLO Gel vs. Placebo for the Treatment of Chemotherapy Induced Peripheral Neuropathy: A Phase III Randomized Double-Blind Placebo Controlled Study

This study is open to RMC Patients only. To register a patient, access the NCCTG web page at <https://ncctg.mayo.edu/training> and enter the remote registration/randomization application.

Has the patient ever been on a prior study entered through this Registration Office? Yes No

If yes: Prior study number _____; prior patient study ID number _____

Registration date (date on) (mm/dd/yyyy) __ __/ __ __/ __ __ __ __
Patient study ID number (provided at time of Reg/Random) _____
NCCTG member (participant sponsor) _____
NCCTG treating location _____
NCCTG treating physician/Allied health professional _____
Institution patient number (local subject number) _____
IRB approval date (mm/dd/yyyy) __ __/ __ __/ __ __ __ __

Patients initials (last, first, middle) _____ (For Mayo Rochester patients, include first four letters of last name.)	Race (check all that apply)
Gender (check one) <input type="checkbox"/> Male <input type="checkbox"/> Female <input type="checkbox"/> Unknown	<input type="checkbox"/> White
Patient's Date of Birth (mm/dd/yyyy) __ __/ __ __/ __ __ __ __	<input type="checkbox"/> Black or African American
Patient's Zip code (USA) _____	<input type="checkbox"/> Native Hawaiian or Other Pacific Islander
Country of Residence (if not USA) _____	<input type="checkbox"/> Asian
Method of payment (check one)	<input type="checkbox"/> American Indian or Alaska Native
<input type="checkbox"/> PI (Private Insurance)	<input type="checkbox"/> Not reported: Patient refused or data not available
<input type="checkbox"/> MR (Medicare)	<input type="checkbox"/> Unknown: Patient is unsure of race
<input type="checkbox"/> MRP (Medicare and Private Insurance)	
<input type="checkbox"/> MD (Medicaid)	Ethnicity (check one)
<input type="checkbox"/> MM (Medicaid and Medicare)	<input type="checkbox"/> Not Hispanic or Latino
<input type="checkbox"/> MVA (Military or Veterans Sponsored, Not Otherwise Specified (NOS))	<input type="checkbox"/> Hispanic or Latino
<input type="checkbox"/> MS (Military Sponsored [including CHAMPUS & TRCARE])	<input type="checkbox"/> Not reported: Patient refused or data not available
<input type="checkbox"/> MV (Veterans Sponsored)	<input type="checkbox"/> Unknown: Patient is unsure of their ethnicity
<input type="checkbox"/> SP (Self pay [no insurance])	
<input type="checkbox"/> NP (No means of payment [no insurance])	
<input type="checkbox"/> OTH (Other)	
<input type="checkbox"/> UNK (Unknown)	

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Patient study ID number _____

Eligibility Check - Answer questions below (yes/no). All requirements must be confirmed. All dates are to be *mm/dd/yyyy*.

Required Characteristics

Yes No NA

Received, or are currently receiving, neurotoxic chemotherapy (including but not limited to taxanes such as paclitaxel or docetaxel; platinum-based compounds such as carboplatin, cisplatin, or oxaliplatin; or vinca alkaloids such as vincristine or vinblastine, or other neurotoxic chemotherapy agents such as bortezomib, lenalidomide or thalidomide). Note: Patients on daily chemotherapy will not be eligible for this trial.	_____	_____	
Pain or symptoms of peripheral neuropathy of duration \geq 1 month attributed to chemotherapy.	_____	_____	
A score of \geq 4 out of 10 on the numbness/tingling/pain numeric analogue scale (see Appendix VII). Score: _____	_____	_____	
\geq 18 years of age. Age = _____.	_____	_____	
Ability to sign informed consent and understand the nature of a placebo-controlled trial.	_____	_____	
ECOG Performance Status (PS) of 0, 1, or 2. PS = _____.	_____	_____	
Ability to complete questionnaires by themselves or with assistance.	_____	_____	
Life expectancy \geq 4 months.	_____	_____	
Creatinine \leq 1.5 X UNL obtained \leq 90 days prior to registration. Creatinine = _____; UNL = _____ Creatinine Date (<i>mm/dd/yyyy</i>): ____ / ____ / ____	_____	_____	
Neuropathy limited to either hands or feet (or both) where gel can be applied.	_____	_____	
Women who are not able to bear children. Note: This is defined by those who are menopausal (12 months and no menstrual period if natural menopause), have had a hysterectomy and/or oophorectomy, permanent surgical sterilization (tubal ligation).	_____	_____	

All responses in above section must be “Yes” unless specified as “NA.”

Contraindications

Yes No NA

Pre-existing or history of peripheral neuropathy due to any cause other than chemotherapy (diabetes, alcohol, toxin, hereditary, etc.).	_____	_____	
History of an allergic reaction to amitriptyline HCl, baclofen, and/or ketamine.	_____	_____	
Treatment \leq 30 days with anticonvulsants, tricyclic antidepressants, MAO inhibitor, or other neuropathic pain medication agents such as carbamazepine, phenytoin, valproic acid, gabapentin, lamotrigine, topical lidocaine patch or gel, capsaicin cream, amifostine, etc. Note: Patients who have taken any of these agents for peripheral neuropathy for \leq 1 week during the past 30 days, but are no longer taking the agent, are not excluded.	_____	_____	
Diagnosis of coronary artery disease including but not limited to MI, PTCA, or CABG \leq 5 years or diagnosis of congestive heart failure of any NY heart class I-IV. Note: Valve replacements are permitted as long as patient has fully recovered from the surgery.	_____	_____	
Other medical conditions, which in the opinion of the treating physician/allied health professional would make this protocol unreasonably hazardous for the patient.	_____	_____	
Current use of any of the study agents in any manner.	_____	_____	
Skin abnormalities at the intended application sites (hands and feet) of study gel (i.e.: skin breakdown)	_____	_____	
Any of the following: <ul style="list-style-type: none"> • Pregnant • Nursing women • Women of childbearing potential 	_____	_____	

All responses in above section must be “No” unless specified as “NA.”

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Patient study ID number _____

Registration Check - Answer questions below (yes/no). All requirements must be confirmed. All dates are to be mm/dd/yyyy.

	Yes	No	NA
Consent form signed and dated. Date of consent ___/___/____.	___	___	___
Authorization for use and disclosure of protected health information signed and dated. Non-USA institution only (check NA) vs. Date of authorization ___/___/____.	___	___	___
Treatment on this protocol must commence at the accruing membership under the supervision of an NCCTG member physician or allied health professional.	___	___	___
Treatment cannot begin prior to registration and must begin ≤28 days after registration.	___	___	___
Pretreatment tests/procedures (see Section 4.0) must be completed ≤30 days prior to registration. Earliest pretreatment test date ___/___/____; latest pretreatment test date ___/___/____	___	___	___
All required baseline symptoms (see Section 10.3) must be documented and graded.	___	___	___
Study drug availability is checked.	___	___	___
Patient questionnaire booklet availability checked; copies are not acceptable for this submission.	___	___	___
Translational Research (Mayo Clinic Rochester patients only): An optional translational research component is part of the Continuation Phase of the study for Mayo Clinic Rochester patients only. There will be an option to select if the patient is to be registered onto this component (Section 14.0). • Patient has/has not given permission to give a blood sample for research testing. Not a Mayo Clinic Rochester Patient (check NA).	___	___	___

All responses in above section must be “Yes” unless specified as “NA.”

Stratification Factors

Chemotherapy with a neurotoxic agent (select one):

- ___ Active (completed)
- ___ Non-active (discontinued)

Use of opioids or oral pain medications (select one):

- ___ Yes
- ___ No

Eligibility Pain Rating (select one – see Section 3.13 and Appendix VII):

- ___ 4 - 7
- ___ 8 – 10

Previous ineffective pharmacologic treatment for peripheral neuropathy (select one):

- ___ Yes
- ___ No

Assigned Treatment

_____ Amitriptyline HCL/baclofen/ketamine gel vs. placebo

Person registering _____ Signature Reg. office specialist _____ initials

Physician _____ Signature _____ M - D - Y